Therapeutic Goods Regulations 1990

Statutory Rules No. 394, 1990

made under the

Therapeutic Goods Act 1989

Compilation No. 114

Compilation date:	1 July 2023
Includes amendments up to:	F2023L00770
Registered:	12 July 2023

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About this compilation

This compilation

This is a compilation of the *Therapeutic Goods Regulations 1990* that shows the text of the law as amended and in force on 1 July 2023 (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 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 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.

Editorial changes

For more information about any editorial changes made in this compilation, see 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 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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.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

Part 1—Preliminary

1 Name of Regulations

These Regulations are the *Therapeutic Goods Regulations 1990*.

2 Interpretation

In these Regulations, unless the contrary intention appears:

active ingredient, for a medicine, means a therapeutically active component in the medicine's final formulation that is responsible for its physiological or pharmacological action.

AHPRA number, of a health practitioner, means the registration number published by the Australian Health Practitioner Regulation Agency in relation to the health practitioner.

analysis includes examination and testing.

antiseptic means a substance:

(a) that is recommended by its manufacturer for:
  (i) dermal application; or
  (ii) application to the mucous membranes of a person or an animal:
    (A) to kill micro organisms; or
    (B) to prevent the growth of micro organisms to a level that causes or may cause clinical infection; and

(b) that is not represented to be suitable for internal use.

Australian Approved Names List means the document entitled Australian Approved Names List for Therapeutic Substances, as in force from time to time, published by the Therapeutic Goods Administration.

Note 1: The Australian Approved Names List includes:
(a) Australian Approved Names—Chemicals List; and
(b) Australian Approved Names—Biological Lists; and
(c) the Herbal Substances AAN List.

Note 2: The Australian Approved Names List may be published as part of a larger document, for example, the document entitled TGA Approved Terminology for Therapeutic Goods.

authorised officer, in relation to a provision of these Regulations, means an officer authorised by the Secretary to exercise powers under that provision.

Note: Regulation 2A provides for the Secretary to authorise certain officers to exercise powers under provisions of these Regulations.

biological medicine means:

(a) a medicine (other than an antibiotic) that is:

(i) a vaccine, a peptide, a protein or polysaccharide-based; and
(ii) derived from a human, animal or other organism, or produced through recombinant technology or biotechnology; and
(iii) of a kind specified in item 1 of Part 1 of Schedule 10; or

(b) a medicine that is a human blood product of a kind mentioned in Appendix A in Part 5 of the Poisons Standard.

biologicals (priority applicant) determination has the meaning given by subsection 32DEA(2) of the Act.

C1 (section 9D) application has the meaning given by Part 1 of Schedule 9.

C1 (section 23) application has the meaning given by Part 1 of Schedule 9.

C2 (section 9D) application has the meaning given by Part 1 of Schedule 9.

C2 (section 23) application has the meaning given by Part 1 of Schedule 9.

C3 (section 9D) application has the meaning given by Part 1 of Schedule 9.

C3 (section 23) application has the meaning given by Part 1 of Schedule 9.

C4 (section 9D) application has the meaning given by Part 1 of Schedule 9.

C4 (section 23) application has the meaning given by Part 1 of Schedule 9.

changes table means the table published on the Department's website for the purposes of this definition, as in force from time to time.

Class 1 biological means a biological (other than an export only biological) that is mentioned in Schedule 16 as a Class 1 biological.

Class 1 IVD medical device has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Class 2 biological means a biological (other than an export only biological):

(a) that:
(i) has been subjected to only minimal manipulation; and
(ii) is only for homologous use; and
(iii) is not mentioned in Schedule 16 as a Class 1, 3 or 4 biological; or

(b) that is mentioned in Schedule 16 as a Class 2 biological.

Class 2 IVD medical device has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Class 3 biological means a biological (other than an export only biological):

(a) that is not a Class 1, 2 or 4 biological; or
(b) that is mentioned in Schedule 16 as a Class 3 biological.

Class 3 IVD medical device has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Class III medical device has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Class 4 biological means a biological (other than an export only biological) that is mentioned in Schedule 16 as a Class 4 biological.

Class 4 IVD medical device has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

complementary medicine means a therapeutic good consisting wholly or principally of 1 or more designated active ingredients, each of which has a clearly established identity and a traditional use.

designated active ingredients, for a complementary medicine, means an active ingredient, or a kind of active ingredient, mentioned in Schedule 14.

designated orphan drug means a medicine in relation to which a designation under regulation 16J is in force.

disinfectant means a substance:

(a) that is recommended by its manufacturer for application to an inanimate object to kill micro organisms; and

(b) that is not represented by the manufacturer to be suitable for internal use.

expiry date, for therapeutic goods, means the date (expressed as the month and year) after which the goods should not be used.

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.

Finance Minister means the Minister who administers the *Public Governance, Performance and Accountability Act 2013.*

fungicide means a chemical agent that kills a fungus or spores of a fungus.

generic product means a medicine that, in comparison to a registered medicine or a medicine that has been registered but is no longer a registered medicine (the ***comparison medicine***):

(a) has the same quantitative composition of therapeutically active substances, being substances of similar quality to those used in the comparison medicine; and

(b) has the same pharmaceutical form; and

(c) is bioequivalent; and

(d) has the same safety and efficacy properties.

gene therapy means the in vivo transfer of DNA or RNA into the cells of human recipients.

herbal substance means all or part of a plant or substance (other than a pure chemical or a substance of bacterial origin):

(a) that is obtained only by drying, crushing, distilling, extracting, expressing, comminuting, mixing with an inert diluent substance or another herbal substance or mixing with water, ethanol, glycerol or aqueous ethanol; and
(b) that is not subjected to any other treatment or process other than a treatment or process that is necessary for its presentation in a pharmaceutical form.

high level disinfectant means a disinfectant that kills all microbial pathogens, except bacterial endospores, when used as recommended by its manufacturer.

homoeopathic preparation means a preparation:
(a) formulated for use on the principle that it is capable of producing in a healthy person symptoms similar to those which it is administered to alleviate; and
(b) prepared according to the practices of homoeopathic pharmacy using the methods of:
(i) serial dilution and succussion of a mother tincture in water, ethanol, aqueous ethanol or glycerol; or
(ii) serial trituration in lactose.

homologous use: see regulation 3B.

hospital grade disinfectant means a disinfectant that is represented to be suitable for therapeutic use:
(a) in premises used for:
(i) the investigation or treatment of a disease, ailment or injury; or
(ii) procedures that are carried out involving the penetration of the human skin; or
(b) in connection with:
(i) the business of beauty therapy or hairdressing; or
(ii) the practice of podiatry;
but does not include:
(c) an antibacterial clothes preparation; or
(d) a sanitary fluid; or
(e) a sanitary powder; or
(f) a sanitiser.

household grade disinfectant means a disinfectant that is not:
(a) an antibacterial clothes preparation; or
(b) a hospital grade disinfectant; or
(c) a sanitary fluid; or
(d) a sanitary powder; or
(e) a sanitiser.

immediate family, in relation to a person, means the parents, grandparents, spouse, *de facto* spouse, child or ward of that person.

IN1 application means an application made under subsection 26BD(1) of the Act for a recommendation to vary a section 26BB determination, if the variation is of a kind that requires:

(a) an evaluation of the safety and quality of an ingredient based on evaluation reports from a competent regulatory authority of a foreign country or foreign jurisdiction determined under regulation 16GJ; or

(b) an evaluation of:

(i) the safety of an ingredient based on evaluation reports from a competent regulatory authority of a foreign country or foreign jurisdiction determined under regulation 16GJ; and

(ii) the quality of the ingredient based on a monograph contained in a default standard.

IN2 application means an application made under subsection 26BD(1) of the Act for a recommendation to vary a section 26BB determination, if the variation is of a kind that requires:

(a) an evaluation of the safety of an ingredient based on evaluation reports from a competent regulatory authority of a foreign country or foreign jurisdiction determined under regulation 16GJ; and

(b) an independent evaluation of the quality of the ingredient.

IN3 application means an application made under subsection 26BD(1) of the Act for a recommendation to vary a section 26BB determination, if the variation is of a kind that requires:

(a) an evaluation of the quality of an ingredient based on:

(i) evaluation reports from a competent regulatory authority of a foreign country or foreign jurisdiction determined under regulation 16GJ; or

(ii) a monograph contained in a default standard; and

(b) an independent evaluation of the safety of the ingredient.

IN4 application means an application made under subsection 26BD(1) of the Act for a recommendation to vary a section 26BB determination, if the variation is of a kind that requires an evaluation of the safety and quality of an ingredient that is not based on an evaluation report from a competent regulatory authority of a foreign country or foreign jurisdiction determined under regulation 16GJ.

independent evaluation means an evaluation that is not based on an evaluation report from a competent regulatory authority of a foreign country or foreign jurisdiction determined under regulation 16GJ.

in-house IVD medical device has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

IVD device means an IVD medical device:

(a) that is:

(i) a Class 1 IVD medical device; or

(ii) a Class 2 IVD medical device; or

(iii) a Class 3 IVD medical device; or

(iv) a Class 4 IVD medical device; and

(b) that is not an in-house IVD medical device.

IVD medical device has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

joint replacement medical device has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

L(A)1 application means an application made under section 23 of the Act to list a medicine under section 26AE of the Act, if the medicine is identical to a medicine listed under section 26AE of the Act (disregarding differences between presentation, colour, flavour or fragrance).

L(A)2 application means an application made under section 23 of the Act to list a medicine under section 26AE of the Act, if:

(a) the application is for a medicine that, in comparison to a medicine (the ***included medicine***) that is or was listed under section 26AE of the Act:

(i) has the same quantitative composition of therapeutically active substances, being substances of similar quality to those used in the included medicine; and

(ii) has the same pharmaceutical form; and

(iii) is bioequivalent; and

(iv) has the same safety and efficacy properties; or

(b) the application requires an evaluation of the efficacy of the medicine based on evaluation reports from a competent regulatory authority of a foreign country or foreign jurisdiction determined under regulation 16GJ.

L(A)3 application means an application made under section 23 of the Act to list a medicine under section 26AE of the Act, if:

(a) either:

(i) the application requires an independent evaluation of the efficacy of the medicine; or

(ii) the application is for a medicine that is listed under section 26AE of the Act and is for a different active ingredient, indication, dosage form, strength or excipient; and

(b) the application is not an L(A)1 application or an L(A)2 application.

L(A)C1 (section 9D) request means a request under subsection 9D(1), (2) or (3) of the Act for a variation that:

(a) is of information included in an entry in the Register relating to a medicine that is listed under section 26AE of the Act; and

(b) is of a kind specified in the changes table as an L(A)C1 (section 9D) level change.

L(A)C1 (section 23) application means an application made under section 23 of the Act for the listing under section 26AE of the Act of a medicine (the ***new medicine***), if:

(a) the new medicine is a changed form of a medicine (the ***existing medicine***) listed under section 26AE of the Act; and
(b) the new medicine and the existing medicine are separate and distinct for the purposes of Part 3-2 of the Act, but the new medicine forms part of the same gazetted therapeutic goods group as the existing medicine; and
(c) the change is of a kind specified in the changes table as an L(A)C1 (section 23) level change.

L(A)C2 (section 9D) request means a request under subsection 9D(1), (2) or (3) of the Act for a variation that:
(a) is of information included in an entry in the Register relating to a medicine that is listed under section 26AE of the Act; and
(b) is of a kind specified in the changes table as an L(A)C2 (section 9D) level change.

L(A)C2 (section 23) application means an application made under section 23 of the Act for the listing under section 26AE of the Act of a medicine (the ***new medicine***), if:
(a) the new medicine is a changed form of a medicine (the ***existing medicine***) listed under section 26AE of the Act; and
(b) the new medicine and the existing medicine are separate and distinct for the purposes of Part 3-2 of the Act, but the new medicine forms part of the same gazetted therapeutic goods group as the existing medicine; and
(c) the change is of a kind specified in the changes table as an L(A)C2 (section 23) level change.

L(A)CN (section 9D) request means a request under subsection 9D(1), (2) or (3) of the Act for a variation that:
(a) is of information included in an entry in the Register relating to a medicine that is listed under section 26AE of the Act; and
(b) is of a kind specified in the changes table as an L(A)CN (section 9D) level change.

L(A)CN (section 23) application means an application made under section 23 of the Act for the listing under section 26AE of the Act of a medicine (the ***new medicine***), if:
(a) the new medicine is a changed form of a medicine (the ***existing medicine***) listed under section 26AE of the Act; and
(b) the new medicine and the existing medicine are separate and distinct for the purposes of Part 3-2 of the Act, but the new medicine forms part of the same gazetted therapeutic goods group as the existing medicine; and
(c) the change is of a kind specified in the changes table as an L(A)CN (section 23) level change.

medicinal cannabis products means therapeutic goods that contain, or are manufactured from, any part of a plant of the genus *Cannabis* (including, for example, the flowers, fruiting tops, seeds, stems and leaves of the plant).

mercury means elemental mercury (Hg(0), CAS No. 7439-97-6), and includes mixtures of mercury (including alloys of mercury) with a mercury concentration of at least 95% by weight, but does not include non-Minamata mercury.

mercury-added products means the products listed in Part 1 of Annex A to the Minamata Convention that contain mercury, but does not include:

(a) products essential for civil protection and military uses; or

(b) products for research, calibration of instrumentation, or for use as reference standards; or

(c) if no feasible mercury-free alternative for replacement is available—the following:

(i) switches and relays;

(ii) cold cathode fluorescent lamps and external electrode fluorescent lamps for electronic displays;

(iii) measuring devices; or

(d) products used in traditional or religious practices; or

(e) vaccines containing thiomersal as preservatives.

Minamata Convention means the Minamata Convention on Mercury done at Minamata on 10 October 2013, as in force for Australia from time to time.

Note: The Convention could in 2021 be viewed in the Australian Treaties Library on the AustLII website (http://www.austlii.edu.au).

minimal manipulation: see regulation 3B.

mother tincture means a preparation prepared by the process of solution, extraction or trituration to prepare homoeopathic preparations.

N1 application has the meaning given by Part 1 of Schedule 9.

N2 application has the meaning given by Part 1 of Schedule 9.

N3 application has the meaning given by Part 1 of Schedule 9.

N4 application has the meaning given by Part 1 of Schedule 9.

N5 application has the meaning given by Part 1 of Schedule 9.

new dosage form medicine means a medicine that:

(a) has the same chemical, biological or radiopharmaceutical active ingredient (or fixed combination of such ingredients) as another medicine that is included in the Register; and

(b) has an indication in common with that other medicine; and

(c) does not have the same dosage form as that other medicine.

new indications medicine means a prescription medicine that:

(a) has the same chemical, biological or radiopharmaceutical active ingredient (or fixed combination of such ingredients) as another prescription medicine included in the Register; and

(b) does not have the same indications as that other medicine.

new prescription medicine means a prescription medicine that contains:

(a) a chemical, biological or radiopharmaceutical active ingredient that has not previously been included in an entry in the Register; or

(b) a fixed combination of chemical, biological or radiopharmaceutical active ingredients at least one of which has not previously been included in an entry in the Register.

nicotine vaping product means a medicine that:

(a) contains nicotine in solution; and

(b) is a finished product; and

(c) is intended to be vaporised, and administered by inhalation, using a vaping device.

nonconforming biological means a biological that is included in the Register under Part 3-2A of the Act but does not conform with:

(a) a standard applicable to the biological; or

(b) any manufacturing requirements under the Act for the biological.

non-Minamata mercury means any of the following:

(a) mercury to be used for laboratory-scale research or as a reference standard;

(b) naturally occurring trace quantities of mercury present in:

(i) products such as non-mercury metals, ores or mineral products (including coal); or

(ii) products derived from the products mentioned in subparagraph (i);

(c) unintentional trace quantities of mercury in chemical products.

open shelf life, for therapeutic goods, means the time, after the container holding the goods is opened, after which the goods should not be used.

Note: For ***container***, see Act, subs 3(1).

original cells or tissues: see regulation 3B.

OTC medicine means therapeutic goods mentioned in Part 3 of Schedule 10.

pharmaceutical benefit means a Commonwealth pharmaceutical benefit under the *National Health Act 1953* or the *Veterans' Entitlements Act 1986*.

Poisons Standard has the same meaning as ***current Poisons Standard***.

Practice Guideline has the meaning given by paragraph 12AB(2)(a).

principal investigator, in relation to a clinical trial of therapeutic goods, means the person who is in charge of the conduct of the trial.

quarter means a period of 3 months commencing on 1 January, 1 April, 1 July or 1 October in a year.

RCM1 application means an application made under section 23 of the Act to register a complementary medicine, if the medicine is identical to registered

goods (disregarding differences between presentation, colour, flavour or fragrance).

RCM2 application means an application made under section 23 of the Act to register a complementary medicine, if the application requires an evaluation of the safety, quality and efficacy of the medicine based on evaluation reports from a competent regulatory authority of a foreign country or foreign jurisdiction determined under regulation 16GJ.

RCM3 application means an application made under section 23 of the Act to register a complementary medicine, if:

(a) the application is for a generic product for which bioequivalence data is not needed for the purposes of evaluation of the medicine; or

(b) the application requires an independent evaluation of one of the following:

(i) the safety of the medicine;

(ii) the quality of the medicine;

(iii) the efficacy of the medicine.

RCM4 application means an application made under section 23 of the Act to register a complementary medicine, if:

(a) the application requires an independent evaluation of 2 of the following:

(i) the safety of the medicine;

(ii) the quality of the medicine;

(iii) the efficacy of the medicine; or

(b) the application is for a generic product for which bioequivalence data is needed for the purposes of evaluation of the medicine; or

(c) the application is for a medicine that is registered and is for one or more of the following:

(i) an extension of indications of the medicine;

(ii) new directions for use of the medicine;

(iii) an increase in the target population for the medicine.

RCM5 application means an application made under section 23 of the Act to register a complementary medicine, if:

(a) either:

(i) the application requires an independent evaluation of the safety, quality and efficacy of the medicine; or

(ii) the application is for a medicine that is registered and is for a new dosage form of the medicine, a new active ingredient of the medicine, an increase in the strength of an active ingredient of the medicine or the addition of an excipient not used in complementary medicines at the time the application is made; and

(b) the application is not an RCM1 application, an RCM2 application, an RCM3 application or an RCM4 application.

RCMC1 (section 9D) request means a request made under subsection 9D(1), (2) or (3) of the Act to vary information in the Register for a registered

complementary medicine, if the variation is of a kind specified in the changes table as an RCMC1 (section 9D) level change.

RCMC1 (section 23) application means an application made under section 23 of the Act to register a complementary medicine (the ***new medicine***), if:

(a) the new medicine is a changed form of a registered complementary medicine (the ***existing medicine***); and

(b) the new medicine and the existing medicine are separate and distinct for the purposes of Part 3-2 of the Act, but the new medicine forms part of the same gazetted therapeutic goods group as the existing medicine; and

(c) the change is of a kind specified in the changes table as an RCMC1 (section 23) level change.

RCMC2 (section 9D) request means a request made under subsection 9D(3) of the Act to vary information in the Register for a registered complementary medicine, if the variation is of a kind specified in the changes table as an RCMC2 (section 9D) level change.

RCMC2 (section 23) application means an application made under section 23 of the Act to register a complementary medicine (the ***new medicine***), if:

(a) the new medicine is a changed form of a registered complementary medicine (the ***existing medicine***); and

(b) the new medicine and the existing medicine are separate and distinct for the purposes of Part 3-2 of the Act, but the new medicine forms part of the same gazetted therapeutic goods group as the existing medicine; and

(c) the change is of a kind specified in the changes table as an RCMC2 (section 23) level change.

RCMC3 (section 9D) request means a request made under subsection 9D(3) of the Act to vary information in the Register for a registered complementary medicine, if the variation is of a kind specified in the changes table as an RCMC3 (section 9D) level change.

RCMC3 (section 23) application means an application made under section 23 of the Act to register a complementary medicine (the ***new medicine***), if:

(a) the new medicine is a changed form of a registered complementary medicine (the ***existing medicine***); and

(b) the new medicine and the existing medicine are separate and distinct for the purposes of Part 3-2 of the Act, but the new medicine forms part of the same gazetted therapeutic goods group as the existing medicine; and

(c) the change is of a kind specified in the changes table as an RCMC3 (section 23) level change.

RCMC4 (section 9D) request means a request made under subsection 9D(3) of the Act to vary information in the Register for a registered complementary medicine, if the variation is of a kind specified in the changes table as an RCMC4 (section 9D) level change.

RCMC4 (section 23) application means an application made under section 23 of the Act to register a complementary medicine (the ***new medicine***), if:

(a) the new medicine is a changed form of a registered complementary medicine (the ***existing medicine***); and

(b) the new medicine and the existing medicine are separate and distinct for the purposes of Part 3-2 of the Act, but the new medicine forms part of the same gazetted therapeutic goods group as the existing medicine; and

(c) the change is of a kind specified in the changes table as an RCMC4 (section 23) level change.

Required Advisory Statements for Medicine Labels means the advisory statements specified by the Minister by legislative instrument under subsection 3(5A) of the Act.

sample includes part of a sample.

serious, in relation to a form of a disease, condition, ailment or defect, means a form of the disease, condition, ailment or defect that is:

(a) generally accepted as not being appropriate to be diagnosed or treated without consulting a suitably qualified health care professional; or

(b) generally accepted to be beyond the ability of the average person to evaluate accurately, or treat safely, without regular supervision by a suitably qualified health care professional.

specialist has the same meaning as in the *Health Insurance Act 1973*.

sporicide means a chemical agent that:

(a) kills bacterial spores; and

(b) has the potential to act as a sterilising agent after prolonged contact with an inanimate object.

Standard AS/NZS means a joint Australian and New Zealand Standard published by, or on behalf of, Standards Australia and the body known as Standards New Zealand.

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

sterilant means a chemical agent that kills microbes with the result that the sterility assurance level of a microbial survivor is less than 10^{-6}.

submission has the meaning given by subclause 1(2) in Part 1 of Schedule 9.

TGA notifications process guidance document means Version 4.0 of the document published by the Therapeutic Goods Administration entitled *Notifications process—requests to vary biologicals and registered medicines where quality, safety and efficacy are not affected* (as in force on 21 June 2023).

Note: The TGA notifications process guidance document could in 2023 be viewed on the Therapeutic Goods Administration's website (http://www.tga.gov.au).

the Act means the *Therapeutic Goods Act 1989*.

Therapeutic Goods Administration means that part of the Department known as the Therapeutic Goods Administration.

therapeutic goods (priority applicant) determination has the meaning given by subsection 25AAA(2) of the Act.

trade name, for therapeutic goods of a particular kind, means the commercial name:

(a) given to goods of that kind by the manufacturer; and

(b) under which the goods are supplied.

traditional use, for a designated active ingredient, means use of the designated active ingredient that:

(a) is well documented, or otherwise established, according to the accumulated experience of many traditional health care practitioners over an extended period of time; and

(b) accords with well-established procedures of preparation, application and dosage.

tuberculocide means a chemical agent that kills *Mycobacterium tuberculosis* and related acid-fast bacteria.

turnover of therapeutic goods, for Division 1 (other than Subdivision 3) of Part 7, has the meaning given by subregulation 43AAA(2).

unused emergency biological means a biological to which section 32CG of the Act applies.

unused emergency goods means goods to which section 30G of the Act applies.

virucide means a chemical agent that renders a virus non-infective.

Note: For the definitions of the following terms, see subsection 3(1) of the Act:

- medicine
- poison
- product information
- Secretary.

2A Authorised officers

The Secretary may, in writing, authorise any of the following persons to exercise powers under a specified provision of these Regulations:

(a) an officer of the Department, of another Department or of an authority of the Commonwealth;

(b) an officer of:

(i) a Department of State of a State; or

(ii) a Department or administrative unit of the Public Service of a Territory; or

(iii) an authority of a State or of a Territory;

being a Department, unit or authority that has functions relating to health matters.

3 Corresponding State law

(1) In this regulation:

the Regulations means:

(a) the *Therapeutic Goods Regulations 1990*; and

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

(3) For the definition of ***corresponding State law*** in subsection 3(1) of the Act, each of the following State laws is declared to correspond to the Act and the Regulations:

(a) the *Poisons and Therapeutic Goods Act 1966* (NSW);

(b) the *Poisons and Therapeutic Goods Regulation 2008* (NSW);

(ba) the *Therapeutic Goods (Victoria) Act 2010* (Vic);

(baa) the *Therapeutic Goods Act 2019* (Qld);

(bab) the *Therapeutic Goods Regulation 2021* (Qld);

(bb) the *Controlled Substances Act 1984* (SA);

(bc) the *Controlled Substances (Poisons) Regulations 2011* (SA);

(c) the *Therapeutic Goods Act 2001* (Tas);

(d) the *Therapeutic Goods Regulations 2002* (Tas);

(e) *Medicines, Poisons and Therapeutic Goods Act 2008* (ACT);

(f) *Medicines, Poisons and Therapeutic Goods Regulation 2008* (ACT);

(g) *Medicines, Poisons and Therapeutic Goods Act 2012* (NT);

(h) *Medicines, Poisons and Therapeutic Goods Regulations 2014* (NT).

3AA Unacceptable presentation of therapeutic goods—prescribed class of medicine

For paragraph 3(5)(ca) of the Act, a prescribed class of medicine is medicine for supply in Australia that is not:

(a) a product of a kind mentioned in Part 1 of Schedule 10; or

(b) a medicine that satisfies the following requirements:

(i) the medicine's label does not contain the advisory statement specified by the Minister under subsection 3(5A) of the Act for the medicine;

(ii) the Secretary has given consent, under sections 14 and 14A of the Act, for the medicine to be imported into, exported from or supplied in Australia without the advisory statement mentioned in subparagraph (i);

(iii) the medicine complies with the terms of the Secretary's consent mentioned in subparagraph (ii); or

(c) a medicine that satisfies the following requirements:

(i) the medicine only contains ingredients that are specified in a determination under paragraph 26BB(1)(a) of the Act;

(ii) if a determination under paragraph 26BB(1)(b) of the Act specifies requirements in relation to ingredients being contained in the medicine—none of the requirements have been contravened; or

(d) a medicine that satisfies the following requirements:

(i) the medicine only has indications that are covered by a determination under paragraph 26BF(1)(a) of the Act;

(ii) if a determination under paragraph 26BF(1)(b) of the Act specifies requirements in relation to indications—none of the requirements have been contravened.

3A Unacceptable presentations

(1) For paragraph 3(5)(e) of the Act, any labelling, packaging or presentation of therapeutic goods (including novelty dosage forms in the shape of animals, robots, cartoon characters or other similar objects) that is likely to result in those goods being mistaken for or confused with confectionery or toys is an unacceptable presentation of the goods.

(2) For paragraph 3(5)(e) of the Act, the presentation of therapeutic goods is unacceptable if the name applied to the goods is not sufficiently distinctive to allow for the identification of the goods for the purposes of recall.

3B Definitions relating to goods comprising etc. human cells and tissues

(1) This regulation applies to goods that comprise, contain, or are derived from human cells or tissues.

(2) The human cells or tissues are the ***original cells or tissues***.

(3) The goods have been subjected to ***minimal manipulation*** if no process or processes to which the goods have been subjected have altered any of the biological characteristics, physiological functions or structural properties of the original cells or tissues that are relevant to the purpose for which the manufacturer of the goods intends the goods to be used.

(4) ***Homologous use*** of the goods is use of the goods to repair, reconstruct, replace or supplement the cells or tissues of a person (the ***recipient***), if the goods will perform the same basic function or functions in the recipient as the original cells or tissues performed in the person from whom they were collected.

3C Classes of biologicals

For the purposes of section 32AA of the Act, the prescribed classes of biologicals are the following:

(a) Class 1 biological;

(b) Class 2 biological;

(c) Class 3 biological;

(d) Class 4 biological;

(e) export only biological.

Part 2—Advertisements

Division 1—Application of Part

4 Application of Part 2

(1) This Part applies to advertisements to which Part 5-1 of the Act applies.

(2) For subsection 42AA(2) of the Act, the bodies mentioned in Schedule 1 are prescribed.

4A Interpretation

A term used in this Part and in Part 5-1 of the Act has the same meaning in this Part as it has in Part 5-1 of the Act.

Note: See section 42B of the Act for definitions of terms used in Part 5-1 of the Act.

Division 3—General provisions about advertising therapeutic goods

6AA Prescribed committees

For paragraph 42DF(4)(b) of the Act, the following committees are prescribed:

(a) Advisory Committee on Medicines;
(b) Advisory Committee on Complementary Medicines;
(c) Advisory Committee on Medical Devices;
(d) Advisory Committee on Vaccines.

6B Prohibited and required representations

Prohibited representations

(1) For the purposes of subsection 42DJ(1) of the Act:
(a) the representations in column 2 of an item in the table in Part 1 of Schedule 2 are specified; and
(b) the therapeutic goods in column 3 of that item are specified.

Note: Under subsection 42DJ(1) of the Act, those representations about those goods are prohibited representations.

Required representations

(2) For subsection 42DJ(2) of the Act, the representations in column 2 of an item in Part 2 of Schedule 2 about therapeutic goods in column 3 of that item are required representations.

7 Prescribed goods for advertising offence and civil penalty

For the purposes of subsections 42DL(12) and 42DLB(9) of the Act, the therapeutic goods are the following:

(a) therapeutic goods that are the subject of an approval or authority under section 19 of the Act;
(b) a medical device, or a kind of medical device, that is the subject of an approval under section 41HB of the Act or an authority under section 41HC of the Act;
(c) medicines covered by an exemption under subregulation 12A(1);
(d) therapeutic goods specified in item 1 of Schedule 5;
(e) therapeutic goods or classes of therapeutic goods mentioned in column 2 of an item in Schedule 5A;
(f) a kind of medical device mentioned in item 1.1 in Part 1 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002*;
(g) a kind of medical device mentioned in column 2 of an item in Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (except items 2.12, 2.13, 2.14 and 2.15 of that Part);

(h) a kind of medical device covered by an exemption under regulation 7.2 of the *Therapeutic Goods (Medical Devices) Regulations 2002*;

(i) therapeutic goods that are neither the subject of an exemption, approval or authority under the Act nor an exemption, approval or authority under regulations under the Act;

(j) therapeutic goods that:

(i) are, or contain, a substance that is included in Schedule 3, 4 or 8 to the current Poisons Standard and is not included in Appendix H to the current Poisons Standard; and

(ii) are extemporaneously compounded for a particular person for therapeutic application to that person.

7A Publisher exception for civil penalty provisions

For the purposes of paragraphs 42DLB(10)(a) and 42DMA(2)(a) of the Act, a kind of person is a publisher of a print edition of a newspaper or magazine that is or was available to the public by way of purchase in Australia.

Division 4—Generic information about ingredients or components of therapeutic goods

8 Compliance with the Code

For section 42DO of the Act, sections 8, 9, 10, 11, 12, 24 (to the extent that it relates to endorsements) and 26 of the Therapeutic Goods Advertising Code are prescribed.

Note: The application of those sections is affected by sections 5 and 6 of the Code.

Part 2A—Patient information

9A Information about certain therapeutic goods to be supplied

(1) The sponsor of therapeutic goods that are specified in Part 1 of Schedule 10 and are included in the Register must not supply the goods if the sponsor does not supply with the goods written information about the goods that meets the requirements for a consumer medicine information document set out in Schedule 12.

Penalty: 10 penalty units.

Note: Additional information must be provided in relation to certain therapeutic goods (other than medical devices) that are manufactured using a human embryo or human embryonic stem cell, or any other material sourced from a human embryo or human embryonic stem cell—see regulation 9B.

(1AAA) For subregulation (1), strict liability applies to the physical element that the goods are specified in Part 1 of Schedule 10.

Note: For ***strict liability***, see section 6.1 of the *Criminal Code*.

(1AA) It is a defence to a prosecution under subregulation (1) if the goods are specified in Schedule 3 to the Poisons Standard.

Note: A defendant bears an evidential burden in relation to the matters mentioned in subregulation (1AA) (see section 13.3 of the *Criminal Code*).

(1A) The sponsor of therapeutic goods that are:

(a) specified in Schedule 3 of the Poisons Standard; and

(b) approved for registration on or after 4 July 1995; and

(c) included in the Register;

must not supply the goods if the sponsor does not supply with the goods written information about the goods that meets the requirements for a consumer medicine information document set out in Schedule 13.

Penalty: 10 penalty units.

(1B) For the purposes of an offence under subregulation (1A), strict liability applies to the physical element mentioned in paragraph (1A)(a).

Note: For ***strict liability***, see section 6.1 of the *Criminal Code*.

(2) For the purposes of subregulation (1) or (1A), information must be provided:

(a) in the primary pack in which the therapeutic goods are supplied; or

(b) in another manner that will enable the information to be given to a person to whom the goods are administered or otherwise dispensed.

9B Information about therapeutic goods manufactured using human embryos

(1) A sponsor of therapeutic goods (other than medical devices) commits an offence if:

(a) the sponsor supplies the goods on or after 1 July 2004; and

(b) the sponsor knows the goods were manufactured using a human embryo or human embryonic stem cell, or other material sourced from a human embryo or human embryonic stem cell; and

(c) the goods are of a kind specified in Part 1 of Schedule 10; and

(d) on or after 1 July 2004, the goods are included in the part of the Register for goods known as registered goods or in the part of the Register for goods known as provisionally registered goods; and

(e) the goods are supplied without written information stating that the goods were manufactured using a human embryo or human embryonic stem cell, or other material sourced from a human embryo or human embryonic stem cell.

Penalty: 10 penalty units.

(2) Strict liability applies to the physical elements mentioned in paragraphs (1)(c), (d) and (e).

(3) The information in relation to the therapeutic goods must be included in:

(a) the consumer medicine information document required under regulation 9A; and

(b) the product information in relation to the goods.

(4) In this regulation:

human embryo means a live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means.

human embryonic stem cell means undifferentiated cells derived from a human embryo that have the potential to become a wide variety of specialised cell types.

(5) For the purposes of the definition of ***human embryo*** in subregulation (4), in working out the length of the period of development of a human embryo, any period when the development of the embryo is suspended is to be disregarded.

Part 2C—Australian Register of Therapeutic Goods

Division 2C.1—Registered and listed therapeutic goods

10 Goods to be included in parts of the Register (Act s 9A)

For paragraph 9A(4)(a) of the Act:

(a) subject to paragraph (aa), therapeutic goods, and classes of therapeutic goods, of a kind mentioned in Schedule 3 that are included in the Register are to be included in the part of the Register for goods known as registered goods; and

(aa) therapeutic goods, and classes of therapeutic goods, of a kind mentioned in Schedule 3 that are included in the Register as mentioned in paragraph 29(2)(c) of the Act are to be included in the part of the Register for goods known as provisionally registered goods; and

(b) therapeutic goods, and classes of therapeutic goods, of a kind mentioned in Schedule 4 that are included in the Register are to be included in the part of the Register for goods known as listed goods.

10AAA Variation of entries in Register—registered complementary medicines and registered OTC medicines

Kinds of variations

(1) For the purposes of paragraph 9D(2C)(b) of the Act, a variation of an entry in the Register that relates to a registered complementary medicine or registered OTC medicine and is listed in the table in subregulation (2) is specified.

Conditions

(2) For the purposes of paragraph 9D(2C)(c) of the Act, the following conditions are specified in relation to a variation of an entry in the Register that is listed in column 2 of an item in the following table:

(a) the variation reflects a change that will be made to, or in relation to, the medicine;

(b) the other conditions set out in the TGA notifications process guidance document in relation to the code listed in column 3 of the item are satisfied.

Kinds of variations—registered complementary medicines and registered OTC medicines

Column 1	Column 2	Column 3
Item	**Variation**	**Code**
1	The addition of a flash including the term “new” or “value pack” to a label or package insert for the medicine	LLN

Kinds of variations—registered complementary medicines and registered OTC medicines		
Column 1	**Column 2**	**Column 3**
Item	**Variation**	**Code**
2	If the name of the medicine's sponsor is not included in the name of the medicine, a change to the sponsor's details (including the sponsor's logo) that are included in a label or package insert for the medicine	LSP
3	A change to the recommended storage conditions for the medicine that are included in a label or package insert for the medicine if the change makes the conditions more restrictive	PSC
4	A decrease in the shelf life of the medicine included in a label or package insert for the medicine	PSR
5	A reduction or removal of an overage for an active ingredient of the medicine	AOV
6	A change to the type of starch (if any) used as an excipient in the medicine	EST
7	Either of the following: (a) if the specifications for the medicine incorporate a default standard—the replacement of that default standard with another default standard; (b) if the specifications for the medicine include in-house tests—the replacement of those tests with a default standard	QFP
8	Either of the following: (a) if the specifications for the starting materials of the medicine incorporate a default standard—the replacement of that default standard with another default standard; (b) if the specifications for the starting materials of the medicine include in-house tests—the replacement of those tests with a default standard	QSP
9	If the medicine is in a solid dosage form, and the container is a blister pack, any of the following changes to a material from which the blister pack is made: (a) if the material is polyvinyl chloride—a change to: (i) a material consisting of polyvinyl chloride and polyvinylidene chloride; or (ii) a material consisting of polyvinyl chloride and polychlorotrifluoroethylene; (b) if the material consists of polyvinyl chloride and polyvinylidene chloride—a change to a material consisting of polyvinyl chloride and polychlorotrifluoroethylene; (c) if the material is used in a plastic component of the blister pack—a change to a material with demonstrated equal or lesser water permeability	KBL
10	If the medicine is in a solid dosage form, and the container is a bottle, any of the following changes to a material from which the bottle is made: (a) if the material is polystyrene—a change to polyvinyl chloride, polyethylene, polypropylene or glass; (b) if the material is polyvinyl chloride—a change to polyethylene, polypropylene or glass;	KBT

Kinds of variations—registered complementary medicines and registered OTC medicines		
Column 1	**Column 2**	**Column 3**
Item	**Variation**	**Code**
	(c) if the material is polyethylene: (i) an increase in the material's density; or (ii) a change to glass, or polypropylene of a density of at least 0.89 grams per cubic centimetre; (d) if the material is glass—a change to polyethylene of a density of at least 0.95 grams per cubic centimetre or polypropylene of a density of at least 0.89 grams per cubic centimetre; (e) if the material is polypropylene of a density of at least 0.89 grams per cubic centimetre—a change to glass, or polyethylene of a density of at least 0.95 grams per cubic centimetre	
11	A change to the closure system for the medicine, unless: (a) the closure system also functions as a metering component of the medicine; or (b) the change involves a change to the pump, or components of the pump, of a metered-dose aerosol	KCL
12	If a refill pack had previously been supplied with the medicine, the supply of the medicine without the refill pack	KRR
13	If the medicine is non-sterile, the performance of an additional step in the manufacture of the medicine by a manufacturer of the medicine	AMS
14	If the medicine is non-sterile, the manufacture of the medicine at an additional site	MMA
15	The cessation of the manufacture of the medicine by a manufacturer	MMD
16	A reduction in the number of steps in the manufacture of the medicine performed by a manufacturer of the medicine	MSD
17	A change to the font, letter height or text size on a label for the medicine, other than a change on the main label for the medicine	LFT
18	Removal of a graphic from a label for the medicine, other than a graphic that relates to directions for: (a) use of the medicine; or (b) use of a measuring device; or (c) use of an applicator	RGN
19	A change to the location of a graphic on the panel of a label for the medicine if: (a) there is no change to the size, shape or colour of the graphic; and (b) the change does not involve reformatting text	LGM
20	If the medicine is in a solid dosage form, the addition of a new pack size that is within the pack size range for the medicine	PSN
21	If the medicine is in a liquid or semi-solid dosage form, the addition of a new pack size that is within the pack size range for the medicine	PLN
22	The deletion of a pack size for the medicine	PSD

Kinds of variations—registered complementary medicines and registered OTC medicines		
Column 1	**Column 2**	**Column 3**
Item	**Variation**	**Code**
23	If the medicine is sterile: (a) the addition of a manufacturer of the medicine for the performance of any of the following steps: (i) release for supply; (ii) secondary packaging; (iii) chemical, physical or microbial testing; or (b) the inclusion of the performance of any of the steps mentioned in paragraph (a) as an additional step in the manufacture of the medicine by a manufacturer of the medicine	MSS
24	If a measuring device had previously been supplied with the medicine, the supply of the medicine without the measuring device, if: (a) other means of accurately measuring the dose are readily available; and (b) any graphical representation of the device (including associated wording) is removed from any label for the medicine; and (c) there are no changes to the directions for use of the medicine	KMO

10AAB Variation of entries in Register—prescription medicines other than biological medicines

Kinds of variations

(1) For the purposes of paragraph 9D(2C)(b) of the Act, a variation of an entry in the Register that relates to a prescription medicine (other than a biological medicine) and is listed in the table in subregulation (2) is specified.

Conditions

(2) For the purposes of paragraph 9D(2C)(c) of the Act, the following conditions are specified in relation to a variation of an entry in the Register that is listed in column 2 of an item in the following table:

(a) the variation reflects a change that will be made to, or in relation to, the medicine;

(b) the other conditions set out in the TGA notifications process guidance document in relation to the code listed in column 3 of the item are satisfied.

Kinds of variations—prescription medicines other than biological medicines		
Column 1	**Column 2**	**Column 3**
Item	**Variation**	**Code**
1	A change to the container or closure system used to store a non-sterile active pharmaceutical ingredient of the medicine	ACCS
2	A change to the synthesis of an active pharmaceutical ingredient of the medicine if:	ACEP

Kinds of variations—prescription medicines other than biological medicines		
Column 1	**Column 2**	**Column 3**
Item	**Variation**	**Code**
	(a) the ingredient is not a synthetic polypeptide; and (b) the ingredient is not prepared by fermentation; and (c) the European Directorate for the Quality of Medicines and Healthcare has reviewed the change; and (d) the Directorate: (i) has issued a revised certificate of suitability in relation to the ingredient; or (ii) has declared that the ingredient does not require a revised certificate of suitability	
3	A change to the size of a manufacturing batch of a non-sterile active pharmaceutical ingredient, or a non-sterile intermediate of such an ingredient, of the medicine	AMBS
4	The cessation of the manufacture of an active pharmaceutical ingredient of the medicine at a manufacturing site	AMCS
5	The introduction, revision or discontinuation of: (a) an in-process control test applied during the manufacture of an active pharmaceutical ingredient, or an intermediate of such an ingredient, of the medicine; or (b) a limit associated with such a test in relation to the manufacture of the ingredient or intermediate	AMIT
7	If an active pharmaceutical ingredient of the medicine is manufactured by multi-step synthesis involving one or more intermediates of the ingredient (including one or more intermediates prepared wholly or partly by fermentation): (a) the transfer of the manufacture of such an intermediate to a different manufacturing site; or (b) the manufacture of such an intermediate at an additional site	AMMF
8	The transfer of the manufacture of a non-sterile active pharmaceutical ingredient of the medicine to a different site, or the manufacture of such an ingredient at an additional site, if: (a) the ingredient is not prepared by fermentation; and (b) the ingredient is a pure chemical entity; and (c) the ingredient is prepared: (i) by chemical synthesis; or (ii) through isolation from a natural source	AMTA
9	A change to a non-biological method used for assaying or residual solvent testing (including testing for water) any of the following: (a) an active pharmaceutical ingredient of the medicine; (b) a starting material for the synthesis of an active pharmaceutical ingredient of the medicine; (c) an intermediate of an active pharmaceutical ingredient of the medicine created in the synthesis of the ingredient	ASAM

Kinds of variations—prescription medicines other than biological medicines		
Column 1	**Column 2**	**Column 3**
Item	**Variation**	**Code**
10	Either of the following: (a) a shortening of the re-test period for an active pharmaceutical ingredient of the medicine; (b) the application of more restrictive storage conditions in relation to an active pharmaceutical ingredient of the medicine	ASDR
11	A change to an identification test used in relation to: (a) an active pharmaceutical ingredient of the medicine; or (b) the starting materials for the synthesis of an active pharmaceutical ingredient of the medicine; or (c) an intermediate of an active pharmaceutical ingredient of the medicine created in the synthesis of the ingredient	ASID
12	A change to the specifications for: (a) an active pharmaceutical ingredient of the medicine; or (b) the starting materials for the synthesis of an active pharmaceutical ingredient of the medicine; or (c) an intermediate of an active pharmaceutical ingredient of the medicine created in the synthesis of the ingredient; if the change makes a limit associated with a test for the ingredient, starting material or intermediate more stringent	ASNL
13	A change, resulting from the addition of a new test and its associated limits, to the specifications for: (a) an active pharmaceutical ingredient of the medicine; or (b) the starting materials for the synthesis of an active pharmaceutical ingredient of the medicine; or (c) an intermediate of an active pharmaceutical ingredient of the medicine created in the synthesis of the ingredient	ASNT
14	A change to the specifications for an active pharmaceutical ingredient of the medicine made for the purposes of ensuring that the specifications are consistent with: (a) a default standard that applies to the medicine; or (b) an order in force under subsection 10(1) of the Act that applies to the medicine	ASPT
15	A change to the size of a manufacturing batch of the dosage form of the medicine if the dosage form is not a modified release dosage form	DMBS
16	A change to the method or equipment used to manufacture the dosage form of the medicine if the dosage form is: (a) semi-solid or liquid; and (b) not a modified release dosage form	DMEL
17	A change to the method or equipment used to manufacture the dosage form of the medicine if the dosage form is: (a) nasal or oral inhalation; and (b) not a modified release dosage form	DMEO

Kinds of variations—prescription medicines other than biological medicines

Column 1	Column 2	Column 3
Item	**Variation**	**Code**
18	A change to the method or equipment used to manufacture the dosage form of the medicine if the dosage form is: (a) solid; and (b) not a modified release dosage form	DMES
19	The introduction, revision or discontinuation of: (a) an in-process control test applied during the manufacture of the medicine; or (b) a limit associated with an in-process control test applied during the manufacture of the medicine	DMIT
20	A reduction or removal of an overage for an active pharmaceutical ingredient of, or excipient (other than an antioxidant) in, the medicine if the dosage form of the medicine is not a modified release dosage form	DMRO
21	A change to the method or equipment used to manufacture the dosage form of the medicine if the dosage form is: (a) sterile; and (b) not a modified release dosage form	DMSE
22	The cessation of the manufacture, or a step in the manufacture, of the medicine at a manufacturing site	DMDM
23	Any of the following: (a) if the dosage form of the medicine is sterile: (i) a change to the location of a site where the labelling and secondary packaging of the medicine are performed; or (ii) the performance of those things at an additional site; (b) if the dosage form of the medicine is not sterile: (i) a change to the location of a site where the labelling and primary and secondary packaging of the medicine are performed; or (ii) the performance of those things at an additional site	DMPL
24	If the dosage form of the medicine is: (a) non-sterile semi-solid or non-sterile liquid; and (b) not a modified release dosage form; either of the following: (c) a change to the location of a site where the medicine is manufactured; (d) the manufacture of the medicine at an additional site	DMSL
25	If the dosage form of the medicine is: (a) non-sterile oral, or non-sterile nasal, inhalation; and (b) not a modified release dosage form; either of the following: (c) a change to the location of a site where the medicine is manufactured; (d) the manufacture of the medicine at an additional site	DMSO

Kinds of variations—prescription medicines other than biological medicines		
Column 1	**Column 2**	**Column 3**
Item	**Variation**	**Code**
26	If the dosage form of the medicine is: (a) non-sterile solid; and (b) not a modified release dosage form; either of the following: (c) a change to the location of a site where the medicine is manufactured; (d) the manufacture of the medicine at an additional site	DMSS
27	Either of the following: (a) a change to the location of a site where either of the following are performed in relation to the medicine: (i) quality control testing (including sterility, microbiological, chemical, physical and bacterial endotoxin or pyrogen testing); (ii) release for supply; (b) the performance of either of the following in relation to the medicine at an additional site: (i) quality control testing (including sterility, microbiological, chemical, physical and bacterial endotoxin or pyrogen testing); (ii) release for supply	DMTR
28	A change to a non-biological method used to assay an active pharmaceutical ingredient of, or an excipient in, the medicine, if the medicine is not a radiopharmaceutical	DSAM
29	A change to one or more tests used to identify an active pharmaceutical ingredient of, or an excipient in, the medicine	DSID
30	A change to the specifications for the medicine made for the purposes of ensuring that the specifications are consistent with a default standard if previously no default standard applied to the medicine	DSIP
31	A change to a limit associated with a test included in the specifications for the medicine if the change makes the limit more stringent	DSNL
32	The addition of a new test and limits associated with the test to the specifications for the medicine	DSNT
33	A minor change to a method used to test physiochemical parameters of the medicine	DSPL
34	A change to the specifications for the medicine made for the purposes of ensuring that the specifications are consistent with: (a) a default standard that applies to the medicine; or (b) an order in force under subsection 10(1) of the Act that applies to the medicine	DSPT
35	A change to a method used to test the sterility of the medicine	DSST
36	If: (a) the medicine is not administered by the parenteral, ophthalmic or intra-tracheal route; and (b) the source of an excipient in the medicine is Category IC ruminant tissue;	EMRS

Kinds of variations—prescription medicines other than biological medicines		
Column 1	**Column 2**	**Column 3**
Item	**Variation**	**Code**
	any of the following: (c) a change in the source of the excipient to a non-animal source; (d) a change in the manufacturing process of the excipient; (e) a change to the location of a manufacturing site	
37	A change to a method used to assay an excipient in the medicine	ESAM
38	A change to the specifications for an excipient in the medicine made for the purposes of ensuring that the specifications are consistent with a default standard that applies to the excipient if previously no default standard applied to the excipient	ESIP
39	A change to the specifications for testing an excipient in the medicine if the change makes the limits applied to the test results more stringent	ESNL
40	A change, resulting from the introduction of a new test and its associated limits, to the specifications for an excipient in the medicine	ESNT
41	A change to the specifications for an excipient in the medicine made for the purposes of ensuring that the specifications are consistent with: (a) a default standard that applies to the medicine; or (b) an order in force under subsection 10(1) of the Act that applies to the medicine	ESPT
42	A change to the outer packaging, or a component of a container, of the medicine if the packaging or component does not touch the dosage form of the medicine	CCCA
43	A change to the size or shape of a container or closure system for the medicine if the medicine is non-sterile	CCSS
44	Any of the following changes to the specifications for a container or closure system for the medicine: (a) the inclusion of a new test; (b) making a limit more stringent; (c) the deletion of a test procedure; (d) a minor change to a test method	CCST
45	If the dosage form of the medicine is non-sterile, and solid or semi-solid, a decrease in the thickness of aluminium foil, or laminate material in laminated aluminium foil, used in blister packs, strip packs or sachets containing the medicine	CMDT
46	An increase in the thickness of material used in a container or closure system for the medicine if the medicine has a dosage form that is: (a) non-sterile; and (b) solid, semi-solid, semi-liquid or liquid	CMIT
47	A change to a label for the medicine to include the name of an excipient in the medicine (whether or not the name is required to be included in the label under an order in force under subsection 10(1) of the Act that applies to the medicine)	LQAE

Kinds of variations—prescription medicines other than biological medicines		
Column 1	**Column 2**	**Column 3**
Item	**Variation**	**Code**
48	A change to a label for the medicine that relates to how the proportion of the medicine that consists of its active ingredient is expressed if the dosage form of the medicine is topical preparation	LQAT
49	A change to a label for the medicine to include the term "hypotonic", "hypertonic" or "isotonic" if the medicine is a large-volume injection	LQHI
50	A change to a label for the medicine to include the release rate of the medicine if the medicine is a transdermal patch	LQRT
51	A change to a label for the medicine to include a warning or cautionary statement that administering the medicine by an incorrect route or method may be hazardous	LWAH
52	A change to a label for the medicine to include a warning or cautionary statement if: (a) the Secretary, under subsection 9D(2) of the Act, has varied the entry in the Register that relates to the medicine to add that warning or cautionary statement; and (b) the Secretary, under subsection 25AA(4) of the Act, has varied the product information that is approved in relation to the medicine under subsection 25AA(1) of the Act to add that warning or cautionary statement	LWSR
53	A change to a physicochemical test method used for testing an active pharmaceutical ingredient of the medicine	ASPC
54	A minor change to: (a) the manufacture of an active pharmaceutical ingredient of the medicine; or (b) a starting material for the synthesis of an active pharmaceutical ingredient of the medicine; or (c) an intermediate of an active pharmaceutical ingredient of the medicine; if the change does not affect any step taken to sterilise the ingredient or intermediate	AMMC
55	A change to a label for the medicine that deletes text from side or rear panels if: (a) the text is present elsewhere on the label for the medicine; and (b) repetition of the information on the panel is not required by an order in force under subsection 10(1) of the Act, or a condition imposed by or under section 28 of the Act, that applies to the medicine	LPDR
56	A change to a label for the medicine to include, remove or amend the name or address of the Australian sponsor or distributor of the medicine	LPCS
57	A change to a label for the medicine to include, remove or change the sponsor's or distributor's logo or livery	LPCL
58	A change to a label for the medicine to remove graphics, pictures or diagrams, and any associated text, other than a pictogram of the medicine or its dosage form	LPDG

Kinds of variations—prescription medicines other than biological medicines		
Column 1	**Column 2**	**Column 3**
Item	**Variation**	**Code**
59	A change to a label for the medicine to include, remove or change a pictogram of the medicine or its dosage form	LPCP
60	A change to a label for the medicine to include: (a) simple instructions or information relating to the packaging of the medicine; or (b) information describing a change in appearance of the dosage form	LPIA
61	A change to a label for the medicine to include or remove text written on the outer protective pouches, or the overwraps, of the container or primary pack of the medicine	LPOP
62	A change to a label for the medicine as a consequence of: (a) a variation, under subsection 9D(3) of the Act, of the entry in the Register that relates to the medicine; or (b) a condition imposed, under subsection 28(3) of the Act, on the listing or registration of the medicine	LOCI
63	A change to a label for the medicine that removes phrases indicating novelty, such as "New formulation" or "New appearance"	LPRP
64	A change to a label for the medicine to include a QR code, if the link is: (a) to a website owned by the person in relation to whom the medicine is included in the Register; and (b) to information that is non-promotional	LPQR
65	A change to a label for the medicine to include information about a patient support program	LPPS

10AAC Variation of entries in Register—biological medicines

Kinds of variations

(1) For the purposes of paragraph 9D(2C)(b) of the Act, a variation of an entry in the Register that relates to a biological medicine and is listed in the table in subregulation (2) is specified.

Conditions

(2) For the purposes of paragraph 9D(2C)(c) of the Act, the following conditions are specified in relation to a variation of an entry in the Register that is listed in column 2 of an item in the following table:
  (a) the variation reflects a change that will be made to, or in relation to, the medicine;
  (b) the other conditions set out in the TGA notifications process guidance document in relation to the code listed in column 3 of the item are satisfied.

Kinds of variations—biological medicines		
Column 1	**Column 2**	**Column 3**
Item	**Variation**	**Code**
1	A change to the specifications for testing the medicine if the change makes the limits associated with the testing more stringent	PSNL
2	A change to the equipment used for quality control testing (including sterility, microbiological, chemical, physical and bacterial endotoxin or pyrogen testing) the medicine	PSQC
3	The release for supply of the medicine at an additional site	PMRS
4	A reduction in the column life of columns used in the purification process for the medicine	PPCR
5	A reduction in the holding time for a drug substance of the medicine, or an intermediate created during the manufacture of such a drug substance, if the medicine is not plasma-derived	PPHR
6	A change to the manufacturer of a filter used in a fermentation process for the medicine	FPFM
7	The introduction of more stringent internal controls on a fermentation process for the medicine	FPNC
8	A reduction in the time required to culture and harvest the cell line for the medicine	FPRP
9	A reduction in the column life of columns used in the plasma fractionation process in the manufacture of the medicine	PFCR
10	The introduction of more stringent internal controls on the plasma fractionation process in the manufacture of the medicine	PFSC
11	A change to the specifications for testing a drug substance or excipient of the medicine if the change makes a limit associated with the testing more stringent	ISNL
12	A change to the specifications for a drug substance or excipient of the medicine made for the purposes of ensuring that the specifications are consistent with: (a) a default standard that applies to the drug substance or excipient; or (b) an order in force under subsection 10(1) of the Act that applies to the drug substance or excipient	ISPT
13	A change to a method used for testing a drug substance or excipient of the medicine if: (a) the change is to adopt a method in a default standard; and (b) the test is not for viral safety	ISAM
14	A change to the specifications for testing the medicine to include a new test and any associated limits if the new test is part of a default standard	PSNT
15	A change to the specifications for the medicine made for the purposes of ensuring that the specifications are consistent with: (a) a default standard that applies to the medicine; or (b) an order in force under subsection 10(1) of the Act that applies to the medicine	PSPT

Kinds of variations—biological medicines		
Column 1	**Column 2**	**Column 3**
Item	**Variation**	**Code**
16	A minor change to a physicochemical test method used for testing the medicine	PMPL
17	The replacement of an in-house reference standard with another if the protocol and acceptance criteria for establishing a replacement in-house reference standard have been approved by the Therapeutic Goods Administration	IRSR
18	A change to a label for the medicine that deletes text from a side or rear panel if: (a) the text is present elsewhere on the label for the medicine; and (b) repetition of the information on the panel is not required by an order in force under subsection 10(1) of the Act, or a condition imposed by or under section 28 of the Act, that applies to the medicine	LPDR
19	A change to a label for the medicine to include, remove or amend the name or address of the Australian sponsor or distributor of the medicine	LPCS
20	A change to a label for the medicine to include, remove or change the sponsor's or distributor's logo or livery	LPCL
21	A change to a label for the medicine to remove graphics, pictures or diagrams, and any associated text, other than a pictogram of the medicine or its dosage form	LPDG
22	A change to a label for the medicine to include, remove or change a pictogram of the medicine or its dosage form	LPCP
23	A change to a label for the medicine to include: (a) simple instructions or information relating to the packaging of the medicine; or (b) information describing a change in appearance of the dosage form	LPIA
24	A change to a label for the medicine to include or remove text written on the outer protective pouches, or the overwraps, of the container or primary pack of the medicine	LPOP
25	A reduction in the shelf life of the drug substance of the medicine	ASRS
26	A reduction in the shelf life of the medicine	PSLD
27	The introduction of anti-tamper packaging if the packaging material is not in contact with the medicine	PPAT
28	Either or both of the following changes to the manufacture of the medicine: (a) removal of a temperature excursion; (b) reduction in the time spent out of refrigeration or freezer storage	PSET
29	The addition of a storage condition for the medicine	PSAR
30	A change to the name or contact details of an albumin manufacturer or supplier, if the site or process has not changed	OAMS

10AAD Variation of entries in Register—biologicals

Kinds of variations

(1) For the purposes of paragraph 9D(3AC)(b) of the Act, a variation:
  (a) of an entry in the Register that relates to a biological; and
  (b) that is listed in the table in subregulation (2);
is specified.

Conditions

(2) For the purposes of paragraph 9D(3AC)(c) of the Act, the following conditions are specified in relation to a variation of an entry in the Register that is listed in column 1 of an item in the following table:
  (a) the variation reflects a change that will be made to, or in relation to, the biological;
  (b) the other conditions set out in the TGA notifications process guidance document in relation to the code listed in column 2 of the item are satisfied.

Kinds of variations—biologicals

Item	Column 1 Variation	Column 2 Code
1	A change to the specifications of the biological for the purposes of ensuring that the specifications are consistent with: (a) a default standard that applies to the biological; or (b) an order in force under subsection 10(1) of the Act that applies to the biological	PT
2	A change to the donor selection criteria for the starting materials for the biological to make the criteria more stringent	DS
3	A change to an infectious disease test kit used to test the starting materials for the biological if the change does not decrease the kit's ability to detect an infectious disease	TK
4	A change to a critical material used in the manufacture of the biological if: (a) the critical parameters for the changed material are equivalent or of greater quality; and (b) the material is not of human or animal origin; and (c) the material is not an excipient; and (d) in the case of critical material that is a container for the biological—the change is not a change to the composition of the material	SM
5	The introduction of more stringent limits to an in-process control test applied during the manufacture of the biological	MI
6	The removal of a product if the biological is a Class 2 biological	BR
7	The addition of a site at which secondary packaging or storage of the biological is performed	MA

Kinds of variations—biologicals		
Item	**Column 1** **Variation**	**Column 2** **Code**
8	A change to the location of a site at which either or both of the following are performed in relation to the biological, or the addition of a site at which either or both of the following are performed in relation to the biological: (a) quality control testing; (b) infectious disease testing	MT
9	The cessation of the manufacture or a step in the manufacture of the biological at a manufacturing site	MR
10	The introduction of more stringent limits to a release test applied during the manufacture of the biological	BS
11	A reduction in the shelf life or shipping timeframe of the biological	BT
12	A change to the label or supporting documentation for the biological to: (a) change the name, address or other contact details of the sponsor, manufacturer or distributor; or (b) change the name of an active ingredient as a result of a change to the Australian Cell and Tissue Name for the ingredient	LC
13	For an export only biological, a change to information included in the entry in the Register for the export only biological	EX

10AA Prescribed requests for variations of entries in Register

(1) A kind of request mentioned in any of the following definitions is prescribed for the purposes of subparagraph 9D(7)(b)(ii) of the Act:

(a) the definition of ***C1 (section 9D) application***;
(b) the definition of ***C2 (section 9D) application***;
(c) the definition of ***C3 (section 9D) application***;
(d) the definition of ***C4 (section 9D) application***;
(da) the definition of ***L(A)C1 (section 9D) request***;
(db) the definition of ***L(A)C2 (section 9D) request***;
(dc) the definition of ***L(A)CN (section 9D) request***;
(e) the definition of ***RCMC1 (section 9D) request***;
(f) the definition of ***RCMC2 (section 9D) request***;
(g) the definition of ***RCMC3 (section 9D) request***;
(h) the definition of ***RCMC4 (section 9D) request***.

(2) A request that is made under subsection 9D(3) of the Act to vary information included in an entry in the Register that relates to a medicine that is a product of a kind specified in Part 1 of Schedule 10 to these Regulations is prescribed for the purposes of subparagraph 9D(7)(b)(ii) of the Act.

10AB Change of person in whose name goods are listed or registered

Application

(1) This regulation applies in relation to a person (the ***relevant person***) in relation to whom therapeutic goods are registered or listed.

Death of person

(2) If the relevant person dies, the legal personal representative (the ***notifying person***) of the dead person:
  (a) is taken to be the person in relation to whom the therapeutic goods are registered or listed; and
  (b) must notify the Secretary, in a form or a manner approved by the Secretary, of the death within 3 months after it occurred.

Bankruptcy of person

(3) If the relevant person becomes bankrupt, the trustee in bankruptcy (the ***notifying person***) of the estate of the bankrupt:
  (a) is taken to be the person in relation to whom the therapeutic goods are registered or listed; and
  (b) must notify the Secretary, in a form or a manner approved by the Secretary, of the bankruptcy within 3 months after the relevant person became bankrupt.

Winding up of body corporate

(4) If the relevant person is a body corporate that is being wound up, the liquidator (the ***notifying person***) of the body corporate:
  (a) is taken to be the person in relation to whom the therapeutic goods are registered or listed; and
  (b) must notify the Secretary, in a form or a manner approved by the Secretary, of the winding up within 3 months after the body corporate is wound up.

Transfer or assignment of business

(5) If the relevant person transfers or assigns, in whole or in part, the business to which the therapeutic goods relate or the person's interest in the therapeutic goods and also agrees to transfer or assign the registration or listing of the therapeutic goods in the Register, the person (the ***notifying person***) to whom the business or interest is transferred or assigned:
  (a) is taken to be the person in relation to whom the therapeutic goods are registered or listed; and
  (b) must, within 3 months after the transfer or assignment, in a form or a manner approved by the Secretary, notify the Secretary in writing of the transfer or assignment.

Secretary may request further information

(6) If the notifying person notifies the Secretary of an event under paragraph (2)(b), (3)(b), (4)(b) or (5)(b), the Secretary may, in writing, request the person to provide further information to the Secretary in relation to the event.

Secretary must amend the Register and provide new certificate

(7) If the notifying person notifies the Secretary of an event under paragraph (2)(b), (3)(b), (4)(b) or (5)(b), and the person also provides any further information requested under subregulation (6), the Secretary must:
  (a) amend the Register accordingly; and
  (b) as soon as practicable after amending the Register:
    (i) inform the person of the amendment; and
    (ii) make available to the person a certificate of registration or listing.

10AC Change of name of person

Application

(1) This regulation applies in relation to a person in relation to whom therapeutic goods are registered or listed.

Change of name of person

(2) If the person changes his, her or its name or, being a corporation, amalgamates with another corporation under a name that is different from the name entered in the Register, the person must, within 3 months after the change of name or amalgamation, notify the Secretary, in a form or a manner approved by the Secretary, of the person's new name and the circumstance giving rise to it.

Secretary may request further information

(3) The Secretary may, in writing, request the person to provide further information to the Secretary about the change of name.

Secretary must amend the Register and provide new certificate

(4) If the person notifies the Secretary under subregulation (2) of a new name, and the person also provides any further information requested under subregulation (3), the Secretary must:
  (a) amend the Register by entering the new name as the name of the person in relation to whom the therapeutic goods are registered or listed; and
  (b) as soon as practicable after entering the new name:
    (i) inform the person that the new name has been entered in the Register; and
    (ii) make available to the person a new certificate of registration or listing.

10B Transfers within the Register

(1) The person in whose name goods (other than medical devices) are entered in the part of the Register for listed goods must apply to the Secretary to transfer the entry for the goods:
  (a) if the goods become subject to inclusion in the part of the Register for registered goods—to the part of the Register for registered goods; or
  (b) if the goods are specified by the Secretary to be a biological under subsection 32A(2) of the Act—to the part of the Register for biologicals.

(2) If goods (other than medical devices) that are included in the part of the Register for registered goods become subject to inclusion in the part of the Register for listed goods, the person in whose name the goods are entered in the Register may apply to the Secretary:
  (a) to transfer the entry for the goods to the part of the Register for listed goods; or
  (b) to retain the entry in the part of the Register for registered goods.

(3) If goods (other than medical devices) that are included in the part of the Register for registered goods are specified by the Secretary to be a biological under subsection 32A(2) of the Act, the person in whose name the goods are entered in the Register must apply to the Secretary to transfer the entry for the goods to the part of the Register for biologicals.

(4) If goods that are included in the Register under Part 3-2A of the Act cease to be a biological because of a determination made by the Secretary under subsection 32A(3) of the Act, the person in whose name the goods are included in the Register must apply to the Secretary to transfer the entry for the goods to the part of the Register for:
  (a) listed goods; or
  (b) registered goods; or
  (c) medical devices.

(5) The person in whose name goods are included in the Register under Chapter 4 of the Act as a kind of medical device may apply to the Secretary to transfer the entry for the goods to the part of the Register for registered goods or the part of the Register for listed goods if the goods cease to be a medical device because of a declaration under subsection 41BD(3) of the Act.

(6) The person in whose name goods are included in a part of the Register must apply to the Secretary to transfer the entry for the goods to the part of the Register for biologicals if the goods:
  (a) are included in the Register as a medical device under Chapter 4 of the Act; and
  (b) cease to be a medical device because of a declaration under subsection 41BD(3) of the Act; and
  (c) are a biological.

(7) An application under subregulation (1), (3), (4) or (6) must be made:

(a) if the Secretary notifies the person in whose name the goods are entered in the Register of a reasonable period within which the application must be made—within that period; or

(b) in any other case—within 15 months after the day when the goods:

(i) became subject to inclusion in the part of the Register for registered goods; or

(ii) were specified by the Secretary to be a biological under subsection 32A(2) of the Act.

Penalty: 5 penalty units.

(8) An offence under subregulation (7) is an offence of strict liability.

Note: For ***strict liability***, see section 6.1 of the *Criminal Code*.

(9) In determining a period of notice for paragraph (7)(a), the Secretary must consider:

(a) the ability of the person in whose name the goods are entered in the Register to provide the information necessary to support the transfer of the entry; and

(b) the reasons for the transfer in relation to the protection of the public.

(10) It is not an offence for the sponsor of goods to which subregulation (1), (3), (4) or (6) applies to import, export, supply or manufacture the goods as listed goods, registered goods, medical devices included in the Register under Chapter 4 of the Act or biologicals included in the Register under Part 3-2A of the Act until the later of:

(a) expiry of the time for making the application under subregulation (7); or

(b) if an application is made—when the application is determined.

(11) An application under this regulation is taken to be an application for registration, listing or inclusion of the goods.

10C Re-assignment of registration or listing numbers

(1) A person in whose name therapeutic goods or grouped therapeutic goods are registered or listed may apply for the therapeutic goods to be assigned a different registration or listing number.

(2) An application:

(a) must be made in writing to the Secretary and delivered to an office of the Department; and

(b) must have with it written information in such detail as is reasonably necessary to allow the application to be properly considered; and

(c) may contain a nomination referred to in subparagraph (6)(b)(ii).

(3) The Secretary may assign to therapeutic goods that:

(a) were grouped therapeutic goods when a registration or listing number was assigned, or last assigned, to the goods; and

(b) are not grouped therapeutic goods when:

(i) the application is decided; or

(ii) an order is made under section 16 of the Act in relation to the goods;

a registration or listing number that is not assigned to other therapeutic goods or grouped therapeutic goods.

(5) The Secretary must assign to therapeutic goods that:

(a) were not grouped therapeutic goods when a registration or listing number was assigned, or last assigned, to the goods; and

(b) are grouped therapeutic goods when:

(i) the application is decided; or

(ii) an order is made under section 16 of the Act in relation to the goods;

a registration or listing number in accordance with subregulation (6).

(6) The Secretary:

(a) may assign to grouped therapeutic goods to which subregulation (5) applies another registration or listing number; and

(b) must assign to those goods a registration or listing number that:

(i) was assigned, or last assigned, to the goods; and

(ii) is nominated by the person in whose name the goods are registered or listed;

not being a registration or listing number that is assigned to other therapeutic goods or grouped therapeutic goods.

10D Notice of reassignment of registration or listing numbers

The Secretary must give notice, in writing, to a person in whose name therapeutic goods, or kinds of therapeutic goods, are registered or listed if a registration or listing number is assigned to the goods under regulation 10C.

Division 2C.2—Medical devices included in the Register under Chapter 4

10E Goods to be included in part of the Register for medical devices (Act s 9A)

For paragraph 9A(4)(a) of the Act, therapeutic goods, and classes of therapeutic goods, that are medical devices and that are included in the Register under Chapter 4 of the Act are to be included in the part of the Register for medical devices.

10F Change of person in relation to whom a medical device is included in the Register under Chapter 4 of the Act

Application

(1) This regulation applies in relation to a person (the ***relevant person***) in relation to whom a kind of medical device is included in the Register under Chapter 4 of the Act.

Death of person

(2) If the relevant person dies, the legal personal representative (the ***notifying person***) of the dead person:
  (a) is taken to be the person in relation to whom the kind of device is included in the Register under Chapter 4 of the Act; and
  (b) must notify the Secretary, in a form or a manner approved by the Secretary, of the death within 3 months after it occurred.

Bankruptcy of person

(3) If the relevant person becomes bankrupt, the trustee in bankruptcy (the ***notifying person***) of the estate of the bankrupt:
  (a) is taken to be the person in relation to whom the kind of device is included in the Register under Chapter 4 of the Act; and
  (b) must notify the Secretary, in a form or a manner approved by the Secretary, of the bankruptcy within 3 months after the relevant person became bankrupt.

Winding up of body corporate

(4) If the relevant person is a body corporate that is being wound up, the liquidator (the ***notifying person***) of the body corporate:
  (a) is taken to be the person in relation to whom the kind of device is included in the Register under Chapter 4 of the Act; and
  (b) must notify the Secretary, in a form or a manner approved by the Secretary, of the winding up within 3 months after the body corporate is wound up.

Transfer or assignment of business

(5) If the relevant person transfers or assigns, in whole or in part, the business to which the kind of medical device relates or the person's interest in the kind of medical device and also agrees to transfer or assign the inclusion of the kind of medical device in the Register, the person (the ***notifying person***) to whom the business or interest is transferred or assigned:

(a) is taken to be the person in relation to whom the kind of medical device is included in the Register under Chapter 4 of the Act; and

(b) must, within 3 months after the transfer or assignment, in a form or a manner approved by the Secretary, notify the Secretary in writing of the transfer or assignment.

Secretary may request further information

(6) If the notifying person notifies the Secretary of an event under paragraph (2)(b), (3)(b), (4)(b) or (5)(b), the Secretary may, in writing, request the person to provide further information to the Secretary in relation to the event.

Secretary must amend the Register and provide new certificate

(7) If the notifying person notifies the Secretary of an event under paragraph (2)(b), (3)(b), (4)(b) or (5)(b), and the person also provides any further information requested under subregulation (6), the Secretary must:

(a) amend the Register accordingly; and

(b) as soon as practicable after amending the Register:

(i) inform the person of the amendment; and

(ii) make available to the person a certificate of the inclusion of the kind of device in the Register under Chapter 4 of the Act.

10FA Change of name of person

Application

(1) This regulation applies in relation to a person in relation to whom a kind of medical device is included in the Register under Chapter 4 of the Act.

Change of name of person

(2) If the person changes his, her or its name or, being a corporation, amalgamates with another corporation under a name that is different from the name entered in the Register in relation to the kind of medical device, the person must, within 3 months after the change of name or amalgamation, notify the Secretary, in a form or a manner approved by the Secretary, of the person's new name and the circumstance giving rise to it.

Secretary may request further information

(3) The Secretary may, in writing, request the person to provide further information to the Secretary about the change of name.

Secretary must amend the Register and provide new certificate

(4) If the person notifies the Secretary under subregulation (2) of a new name, and the person also provides any further information requested by the Secretary under subregulation (3), the Secretary must:

(a) amend the Register by entering the new name as the name of the person in relation to whom the kind of device is included in the Register under Chapter 4 of the Act; and

(b) as soon as practicable after entering the new name:

(i) inform the person that the new name has been entered in the Register; and

(ii) make available to the person a new certificate of the inclusion of the kind of device in the Register under that Chapter.

Division 2C.3—Biologicals included in the Register

10G Goods to be included in the part of the Register for biologicals

For paragraph 9A(4)(a) of the Act, therapeutic goods, and classes of therapeutic goods, that are biologicals and that are included in the Register under Part 3-2A of the Act are to be included in the part of the Register for biologicals.

10H Change of person for whom a biological is included in the Register under Part 3-2A of the Act

Application

(1) This regulation applies to a person (the ***relevant person***) in relation to whom a biological is included in the Register under Part 3-2A of the Act.

Death of person

(2) If the relevant person dies, the legal personal representative (the ***notifying person***) of the dead person:
  (a) is taken to be the person in relation to whom the biological is included in the Register under Part 3-2A of the Act; and
  (b) must notify the Secretary, in a form or a manner approved by the Secretary, of the death within 3 months after it occurred.

Bankruptcy of person

(3) If the relevant person becomes bankrupt, the trustee in bankruptcy (the ***notifying person***) of the estate of the bankrupt:
  (a) is taken to be the person in relation to whom the biological is included in the Register under Part 3-2A of the Act; and
  (b) must notify the Secretary, in a form or a manner approved by the Secretary, of the bankruptcy within 3 months after the relevant person became bankrupt.

Winding up of body corporate

(4) If the relevant person is a body corporate that is being wound up, the liquidator (the ***notifying person***) of the body corporate:
  (a) is taken to be the person in relation to whom the biological is included in the Register under Part 3-2A of the Act; and
  (b) must notify the Secretary, in a form or a manner approved by the Secretary, of the winding up within 3 months after the body corporate is wound up.

Transfer or assignment of business

(5) If the relevant person transfers or assigns, in whole or in part, the business to which the biological relates or the person's interest in the biological and also

agrees to transfer or assign the inclusion of the biological in the Register, the person (the ***notifying person***) to whom the business or interest is transferred or assigned:

(a) is taken to be the person in relation to whom the biological is included in the Register under Part 3-2A of the Act; and

(b) must notify the Secretary, in a form or a manner approved by the Secretary, of the transfer or assignment within 3 months after the transfer or assignment.

Secretary may request further information

(6) If the notifying person notifies the Secretary of an event under paragraph (2)(b), (3)(b), (4)(b) or (5)(b), the Secretary may, in writing, request the person to provide further information to the Secretary in relation to the event.

Secretary must amend the Register and provide new certificate

(7) If the notifying person notifies the Secretary of an event under paragraph (2)(b), (3)(b), (4)(b) or (5)(b), and the person also provides any further information requested by the Secretary under subregulation (6), the Secretary must:

(a) amend the Register accordingly; and

(b) as soon as practicable after amending the Register:

(i) inform the person of the amendment; and

(ii) make available to the person a certificate of the inclusion of the biological in the Register under Part 3-2A of the Act.

10HA Change of name of person

Application

(1) This regulation applies to a person in relation to whom a biological is included in the Register under Part 3-2A of the Act.

Change of name of person

(2) If the person changes his, her or its name or, being a corporation, amalgamates with another corporation under a name that is different from the name entered in the Register in relation to the biological, the person must, within 3 months after the change of name or amalgamation, notify the Secretary, in a form or a manner approved by the Secretary, of the person's new name and the circumstance giving rise to it.

Secretary may request further information

(3) The Secretary may, in writing, request the person to provide further information to the Secretary about the change of name.

Secretary must amend the Register and provide new certificate

(4) If the person notifies the Secretary under subregulation (2) of a new name, and the person also provides any further information requested by the Secretary under subregulation (3), the Secretary must:

(a) amend the Register by entering the new name as the name of the person in relation to whom the biological is included in the Register under Part 3-2A of the Act; and

(b) as soon as practicable after entering the new name:

(i) inform the person that the new name has been entered in the Register; and

(ii) make available to the person a new certificate of the inclusion of the biological in the Register under that Part.

10I Re-assignment of biological numbers

(1) A person in whose name a biological is included in the Register under Part 3-2A of the Act may apply for the biological to be assigned a different biological number.

(2) The application:

(a) must be made in writing to the Secretary and delivered to an office of the Department; and

(b) must have with it written information in sufficient detail to allow the application to be properly considered.

(3) The Secretary may assign to the biological a biological number that is not assigned to another biological.

10J Notice of reassignment of biological numbers

The Secretary must give notice, in writing, to a person in whose name a biological is included in the Register under Part 3-2A of the Act if a biological number is assigned to the biological under regulation 10I.

Part 2CA—Prohibition on import, export or manufacture of certain therapeutic goods—international agreements

Division 1—Prescribed international agreements

10JA Prescribed international agreements

(1) For the purposes of subsection 9K(1) of the Act, the Minamata Convention is prescribed.

(2) For the purposes of subsection 9K(3) of the Act, the Minamata Convention is prescribed.

(3) Unless the contrary intention appears, an expression used in both this Part and the Minamata Convention has the same meaning in this Part as in that Convention.

Division 2—Prohibition on importation of mercury

10JB Importation of a therapeutic good that is mercury from a non-party to the Minamata Convention is prohibited unless approved by the Secretary before importation

For the purposes of paragraph 9K(1)(a) of the Act, the importation into Australia of a therapeutic good that is mercury from a non-party to the Minamata Convention is prohibited unless the Secretary has, in accordance with Division 4, approved, in writing, the importation before the mercury is imported.

Division 3—Prohibition on export of mercury

10JC Export of a therapeutic good that is mercury is prohibited unless approved by the Secretary before exportation

For the purposes of paragraph 9K(1)(b) of the Act, the export from Australia of a therapeutic good that is mercury is prohibited unless the Secretary has, in accordance with Division 4, approved, in writing, the export before the mercury is exported.

Division 4—Applications to import or export mercury

10JD Applications to import or export mercury

(1) A person may apply to the Secretary for approval:
  (a) to import into Australia a therapeutic good that is mercury from a non-party to the Minamata Convention; or
  (b) to export from Australia a therapeutic good that is mercury.

(2) An application must:
  (a) be in the form approved by the Secretary for the purposes of this paragraph; and
  (b) include the information required by the form; and
  (c) be accompanied by the fee (if any) mentioned in Part 2 of Schedule 9 for the application.

(3) An application is taken not to have been made if the application does not comply with the requirements referred to in subregulation (2).

(4) The Secretary may approve a form for the purposes of paragraph (2)(a).

10JE When approval may be granted—importation

The Secretary may approve an application under paragraph 10JD(1)(a) to import a therapeutic good that is mercury from a non-party (the ***exporting party***) to the Minamata Convention only if the Secretary is satisfied that:
  (a) either:
    (i) Australia has provided the exporting party with written consent to the import; or
    (ii) a general notification of consent is in force for Australia in accordance with paragraph 7 of Article 3 of the Minamata Convention; and
  (b) the exporting party has provided written certification that the mercury is neither sourced from primary mercury mining nor excess mercury from the decommissioning of chlor-alkali facilities.

10JF When approval may be granted—export

Export to a Party to the Minamata Convention

(1) The Secretary may approve an application under paragraph 10JD(1)(b) to export a therapeutic good that is mercury to a Party (the ***importing Party***) to the Minamata Convention only if the Secretary is satisfied that :
  (a) the importing Party has provided its written consent to the export; and
  (b) the mercury is to be exported:
    (i) for a use allowed to the importing Party under the Minamata Convention; or

(ii) for environmentally sound interim storage as set out in Article 10 of the Minamata Convention.

Export to a non-party to the Minamata Convention

(2) The Secretary may approve an application under paragraph 10JD(1)(b) to export a therapeutic good that is mercury to a non-party (the ***importing party***) to the Minamata Convention only if the Secretary is satisfied that the importing party has provided:

(a) its written consent to the export; and

(b) its written certification demonstrating that:

(i) it has measures in place to ensure the protection of human health and the environment; and

(ii) it has measures in place to ensure compliance with Articles 10 and 11 of the Minamata Convention; and

(iii) the mercury will be used only for a use allowed under the Minamata Convention to a Party to the Minamata Convention or for environmentally sound interim storage as set out in Article 10 of the Minamata Convention.

Division 5—Mercury-added products

10JG Import, export and manufacture of therapeutic goods that are mercury-added products

For the purposes of subsection 9K(1) of the Act, the importation into, export from and manufacture in, Australia of therapeutic goods that are mercury-added products is prohibited.

10JH Manufacture of therapeutic goods containing mercury-added products

For the purposes of subsection 9K(3) of the Act, the manufacture in Australia of therapeutic goods that contain mercury-added products is prohibited.

Part 2D—Provisional determinations for medicine

10K Applications for provisional determinations

For the purposes of subsection 22C(1) of the Act, the kinds of medicine are the following:

(a) new prescription medicine;

(b) new indications medicine.

10L Provisional determinations

(1) For the purposes of subsection 22D(2) of the Act, the criteria are all of the following:

(a) an indication of the medicine is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition;

(b) either:

(i) no therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods); or

(ii) if one or more therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods)—there is preliminary clinical data demonstrating that the medicine is likely to provide a significant improvement in the efficacy or safety of the treatment, prevention or diagnosis of the condition compared to those goods;

(c) there is preliminary clinical data demonstrating that the medicine is likely to provide a major therapeutic advance;

(d) the person who made the application under subsection 22C(1) of the Act has provided sufficient evidence of the person's plan to submit comprehensive clinical data on the safety and efficacy of the medicine before the end of the 6 years that would start on the day that provisional registration of the medicine would commence if the Secretary were to provisionally register the medicine.

(2) However, paragraphs (1)(b) and (c) do not apply if:

(a) the application under subsection 22C(1) of the Act is made on or after the commencement of this subregulation; and

(b) an indication of the medicine is the treatment or prevention of the disease known as coronavirus disease (COVID-19).

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.

Part 3—Registration, inclusion, listing and exemption of therapeutic goods

11 Characteristics that separate and distinguish certain medicines from other therapeutic goods

(1) For paragraph 16(1A)(d) of the Act, different characteristics are:

(a) a different name; or

(b) different indications; or

(c) a different excipient; or

(d) for medicines that contain any restricted ingredients:

(i) a different quantity of a restricted ingredient that is an excipient; or

(ii) if the restriction on a restricted ingredient relates to its concentration in a relevant medicine—a different concentration of the restricted ingredient; or

(iii) if the restriction on a restricted ingredient relates to its quantity in the recommended single or daily dose in a relevant medicine—different directions for use setting out a different recommended single or daily dose.

(2) A substance is a ***restricted ingredient*** if:

(a) it is an ingredient in a relevant medicine; and

(b) for that medicine to be, or to remain, eligible for listing, the permissible quantity or concentration of the substance in the medicine is restricted by operation of any of the following:

(i) Schedule 4;

(ii) the Poisons Standard;

(iii) a condition imposed under section 28 of the Act;

(iv) a standard under section 10 of the Act;

(vi) any other provision in these Regulations or in the Act that deals with eligibility of medicines for listing.

(3) In this regulation:

relevant medicine means a medicine that is listable goods or listed goods and that is not an export only medicine.

11A Characteristics that separate and distinguish certain biologicals from other biologicals

(1) For section 32AB of the Act:

(a) a Class 1 or Class 2 biological is separate and distinct from other biologicals if any of the following characteristics of the biological differ from other biologicals:

(i) applicable standards;

(ii) intended clinical use;
(iii) principal manufacturer; and

(b) a Class 3 or Class 4 biological is separate and distinct from other biologicals if any of the following characteristics of the biological differ from other biologicals:
(i) product name;
(ii) dosage form;
(iii) formulation or composition;
(iv) therapeutic indication;
(v) type of container, regardless of container size;
(vi) principal manufacturer; and

(c) an export only biological is separate and distinct from other biologicals if any of the following characteristics of the biological differ from other biologicals:
(i) active ingredient;
(ii) dosage form;
(iii) principal manufacturer.

(1A) However, a biological is not separate and distinct from other biologicals under subregulation (1) if:
(a) the biological is separate and distinct from other biologicals under that subregulation by reason only of a difference in a characteristic mentioned in subparagraph (1)(a)(ii) or (1)(b)(iv); and
(b) the difference in that characteristic is the result of a request made under subsection 9D(3AA) of the Act to vary the entry of the biological in the Register.

(2) In this regulation:

principal manufacturer means the person who carries out the total manufacture of a product or, if more than one manufacturer is involved, the person who takes overall responsibility for the manufacture of the product, including releasing the product for supply.

12 Exempt goods

(1) For subsections 18(1) and 32CA(2) of the Act, the therapeutic goods or classes of therapeutic goods mentioned in Schedule 5 are exempt from the operation of the following provisions of the Act:
(a) Part 3-2 (except sections 30EA, 31A and 31C to 31F);
(b) Division 4 of Part 3-2A.

(2) For subsections 18(1) and 32CA(2) of the Act, the therapeutic goods or classes of therapeutic goods mentioned in column 2 of an item in Schedule 5A are exempt from the operation of the following provisions of the Act:
(a) Part 3-2 (except sections 30EA, 31A and 31C to 31F);
(b) Division 4 of Part 3-2A.

(3) The exemptions mentioned in subregulation (2) are subject to compliance with the conditions mentioned in column 3 of an item in Schedule 5A for the therapeutic goods.

(4) If therapeutic goods to which this regulation applies cease to be exempt from the operation of Part 3-2 or Division 4 of Part 3-2A of the Act and the sponsor of the goods applied for registration, listing, or inclusion of the goods in the Register before the exemption ceased, this regulation is taken to apply to the goods until the application for registration, listing or inclusion in the Register is determined.

Limited exemptions

(5) For therapeutic goods exempt under paragraph (a) of item 5 of the table in Schedule 5, the exemption is subject to the condition that the exemption only has effect in relation to the importation.

(6) For therapeutic goods exempt under paragraph (b) of item 5 of the table in Schedule 5, the exemption is subject to the condition that the exemption only has effect in relation to the manufacture.

(7) For therapeutic goods exempt under paragraph (c) of item 5 of the table in Schedule 5, the exemption is subject to the condition that the exemption only has effect in relation to the supply by the intermediate supplier.

12A Unapproved medicines and biological—exemption in life-threatening cases

(1) For the purposes of subsection 18(1) of the Act, all medicines, other than medicines of a class or kind listed in Schedule 9 or 10 to the Poisons Standard, are exempted, subject to subregulation (2), from the operation of Part 3-2 of the Act (except section 31A and sections 31C to 31F).

(1A) For the purposes of subsection 32CA(2) of the Act, and subject to subregulation (2), all biologicals are exempt from the operation of Division 4 of Part 3-2A of the Act.

(2) The exemption of a medicine under subregulation (1), or of a biological under subregulation (1A), is subject to compliance with the following conditions:

(a) the medicine or biological is to be given to a person who satisfies the following criteria:

(i) the person is a Category A patient (as defined in subregulation (5)); and

(ii) the person, or the guardian of the person, has given informed consent (as defined in subregulation (5)) to the medicine or biological being given to the person; and

(iii) a statement in relation to the person, in the form approved by the Secretary for the purposes of this subparagraph, is completed by the medical practitioner by whom, or at whose direction, the medicine or biological is given to the person or by a health practitioner acting on behalf of that medical practitioner; and

(b) the medicine or biological is dispensed on the prescription of a medical practitioner who has prescribed the medicine or biological in accordance with good medical practice.

(2A) An approval of a form referred to in subparagraph (2)(a)(iii) may require information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

(3) A person who completes a statement referred to in subparagraph (2)(a)(iii) in relation to a medicine or biological that is given to a person must send a copy of the statement to the Secretary within 28 days after the medicine or biological is given to the person.

Penalty: 10 penalty units.

(3A) An offence under subregulation (3) is an offence of strict liability.

Note: For ***strict liability***, see section 6.1 of the *Criminal Code*.

(4) This regulation does not affect the operation of regulation 12.

(5) In this regulation:

Category A patient means a person who is seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment.

informed consent, in relation to treatment or proposed treatment, means consent freely given by a person on the basis of information concerning the potential risks and benefits of the treatment that was sufficient information to allow the person to make an informed decision whether to consent to the treatment.

12AAB Disposal of unused emergency goods and unused emergency biologicals

(1) For subsections 30G(2) and 32CG(2) of the Act, Schedule 5B sets out the requirements for an arrangement for disposal of unused emergency goods and unused emergency biologicals.

(2) Nothing in this regulation or in Schedule 5B is taken to prevent a disposal of unused emergency goods if:

(a) the goods have become (whether in relation to an indication for which the goods could have been used under the exemption or in relation to a different indication):

(i) registered goods or listed goods; or

(ii) exempt goods under section 18 of the Act; or

(iii) goods that are the subject of an approval or authority under section 19 of the Act; or

(iv) goods that are the subject of an approval under section 19A of the Act; and

(b) the disposal is in accordance with other provisions of the Act and these Regulations relevant to the goods.

(3) Nothing in this regulation or in Schedule 5B is taken to prevent a disposal of an unused emergency biological if:

(a) the biological has become (whether in relation to an indication for which the biological could have been used under the exemption or in relation to a different indication):

(i) included in the Register under Part 3-2A of the Act; or

(ii) exempt under subsection 32CA(2) of the Act; or

(iii) the subject of an approval or authority under section 32CK or 32CM of the Act; or

(iv) the subject of an approval under section 32CO of the Act; and

(b) the disposal is in accordance with other provisions of the Act and these Regulations relevant to the biological.

12AA Applications for special and experimental uses

Without limiting the information that may be required by the Secretary under subsection 19(2) or 32CK(3) or (4) of the Act, that information may include, for therapeutic goods the subject of an application under subsection 19(1) or 32CK(1) of the Act for a use described in paragraph 19(1)(b) or 32CK (1)(e) of the Act:

(a) the names of the members of the ethics committee that has given approval for each proposed clinical trial of the goods and that will have responsibility for monitoring the conduct of each trial; and

(b) the name of, and the contact details for, the principal investigator for each trial; and

(c) the name of the person who will be in charge of the trial site (or each trial site, if the trial is to be conducted at more than 1 site), unless that person is the principal investigator; and

(d) information about whether or not any conditions specified by the committee have been met.

12AB Goods imported etc for experimental uses

(1) For subsections 19(1A) and 32CK(8) of the Act, this regulation specifies conditions attaching to an approval for the importation or supply of therapeutic goods for use solely for experimental purposes in humans.

(2) Before any clinical trials proposed to be undertaken in relation to the goods are started, the Secretary, must receive from the person to whom the approval is granted, and the principal investigator for each trial site:

(a) a written assurance that clinical trials will be conducted in accordance with the Guideline for Good Clinical Practice (the ***Practice Guideline***), as in force from time to time, published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; and

(b) a written undertaking:

(i) to comply with requests by an authorised officer, whether made before or after the start of the trial, to give information about the conduct of the trial; and

(ii) allow an authorised officer to do the things mentioned in regulation 12AC.

12AC Powers of authorised officers in relation to goods imported etc for experimental uses

(1) An authorised officer may, in relation to a clinical trial mentioned in regulation 12AB or column 2 of item 3 of the table in Schedule 5A:

(a) enter a site of the trial; and

(b) search the site and any thing on the site; and

(c) inspect, examine, take measurements of, or conduct tests on (including by the taking of samples), any thing on the site that relates to the trial; and

(d) take photographs, make video recordings or make sketches of the site or any thing on the site; and

(e) inspect any book, record or document on the site that relates to the trial; and

(f) request the principal investigator to:

(i) answer any questions put by the authorised officer; and

(ii) produce any book, record or document requested by the authorised officer.

(2) An authorised officer is not entitled to do a thing mentioned in subregulation (1) if:

(a) the principal investigator, or any other person present at the site concerned and in apparent control, requests the authorised officer to produce his or her identity card for inspection; and

(b) the authorised officer fails to comply with the request.

Note: For identity cards, see section 52 of the Act.

(3) The principal investigator, or any other person present at the site and in apparent control, is entitled to observe a search conducted under paragraph (1)(b), but must not impede the search.

(4) Subregulation (3) does not prevent 2 or more areas of the site being searched at the same time.

12AD Use of goods for experimental purposes—specified conditions

For subsections 19(4A) and 32CL(1) of the Act, the following conditions are specified:

(a) the use of therapeutic goods in a clinical trial must be in accordance with the Practice Guideline;

(b) the use must comply with a procedural protocol approved by the ethics committee that has the function of monitoring the conduct of the trial at each trial site;

(c) the use must be in accordance with the ethical standards set out in the National Statement on Ethical Conduct in Research Involving Humans, as in force from time to time, published by the National Health and Medical Research Council;

(d) the use must cease if the ethics committee mentioned in paragraph (b) informs the principal investigator that the use is inconsistent with:

(i) the protocol mentioned in paragraph (b); or

(ii) any condition subject to which approval for the use was given.

12B Exemptions for certain uses—medicines

(1) For the purposes of paragraph 19(6)(a) of the Act, in relation to medicines, medical practitioners engaged in clinical practice in or outside a hospital are a prescribed class of medical practitioners.

(1A) For the purposes of subsection 19(6) of the Act, in relation to medicines, paragraph 19(6)(aa) does not apply to a medical practitioner engaged in clinical practice outside a hospital if the medical practitioner:

(a) has demonstrated that, in relation to the proposed supply of the medicines, the medical practitioner does not have access to an ethics committee that could approve the supply; and

(b) has received an endorsement, from a specialist college with established expertise relevant to the use of the medicines, to supply the medicines.

(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**
2	allergens—multiple, various (including control solutions)	drops	intradermal	confirmation of suspected allergic reactions
3	allergens – multiple,	drops	skin prick	confirmation of suspected

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
	various (including control solutions)			allergic reactions
4	amiloride	tablet	oral	treatment of hypokalaemia
4A	argipressin	injection	intravenous	(a) to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines; or (b) treatment of uterine fibroids
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 *Helicobacter Pylori* 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)
9	carbidopa	tablet	oral	premedication for F-18 DOPA imaging
10	colecalciferol	capsule	oral	treatment of severe vitamin D deficiency and prevention of osteoporosis
11	colecalciferol	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

Regulation 12B

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
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 *mycobacterium avium* 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	ciclosporin, 0.05%	eye drops, emulsion	ophthalmic	treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis 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

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
				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
26A	disulfiram	tablet	oral	deterrent to alcohol consumption
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
30A	famotidine	injection	intravenous	prevention and management of hypersensitivity reactions to chemotherapy
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
33	furazolidone	tablet	oral	treatment of resistant

Regulation 12B

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
				Helicobacter Pylori 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	(a) prostate cancer imaging study (b) PET CT gallium-68 PSMA whole body uptake study
36A	ganciclovir	gel	ophthalmic	treatment of cytomegalovirus
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)
40A	iloprost	injection	intravenous infusion	(a) treatment of patients with severe disabling Raynaud's phenomenon; or (b) treatment of peripheral ischaemia
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
42AA	interferon alpha-2b	eye drops	ophthalmic	treatment of ocular surface squamous neoplasia
42A	ketotifen	tablet	oral	treatment of allergic conditions
43	levofloxacin	tablet	oral	treatment of resistant *Helicobacter Pylori* infection or drug resistant tuberculosis

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
44	levomepromazine	tablet	oral	treatment of nausea and vomiting or agitation
45	levomepromazine	injection	subcutaneous	treatment of nausea and vomiting or agitation
45A	lifitegrast	eye drops	ophthalmic	treatment of dry eye disease
46A	lutetium-177 (Lu 177) dotatate	injection	intravenous	treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs)
46B	lutetium-177 (Lu 177) prostate specific membrane antigen (PSMA)	injection	intravenous	treatment of metastatic castration-resistant prostate cancer
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
51A	metolazone	tablet	oral	treatment of fluid overload
52	mexiletine	tablet	oral	treatment of ventricular arrhythmia or myotonic disorders
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
58A	nifedipine	immediate release tablet	oral	(a) treatment of preterm labour; or (b) treatment of pre-eclampsia

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Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
58B	nifedipine	capsule	oral	(a) treatment of preterm labour; or (b) treatment of pre-eclampsia
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) *blastocystis hominis*; (b) *dientomoeba fragilis*; (c) *entamoeba histolytica*; (d) parasite infection
62	pimozide	tablet	oral	treatment of schizophrenia, chronic psychosis or Tourette syndrome
63	pristinamycin	tablet	oral	treatment of confirmed methicillin-resistant *Staphylococcus aureus* or vancomycin-resistant *enterococci* 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 *mycoplasma genitalium* infections; or treatment of other infections as prescribed by an infectious disease specialist
63A	progesterone	injection	subcutaneous	treatment of progesterone deficiency
63B	progesterone in oil	injection	intramuscular	treatment of progesterone deficiency
64	pyrazinamide	tablet	oral	treatment of tuberculosis

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Active ingredient**	**Dosage form**	**Route of administration**	**Indication**
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% hydroxylpropyl 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
72A	Technetium-99m (99m Tc) prostate specific membrane antigen (PSMA)-I&S	injection	intravenous	prostate cancer imaging study
75	tetracycline	capsule	oral	treatment of resistant *Helicobacter Pylori*

Regulation 12B

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 *Helicobacter Pylori* infection
77	tick-borne encephalitis vaccine	injection	intramuscular	prevention of tick-borne encephalitis
78	tinidazole	tablet	oral	treatment of *trichomonas vaginalis* 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
78A	tizanidine	capsule	oral	treatment of spasticity where other treatments have failed
78B	tizanidine	tablet	oral	treatment of spasticity where other treatments have failed
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

(1C) 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 circumstances specified in column 2 of an item in the following table exist in relation to the medicine; and

(b) the medicine is in the dosage form specified in column 3 of that item; and
(c) the medicine is to be administered by the route specified in column 4 of that item; and
(d) the supply is for the indication specified in column 5 of that item.

Specified therapeutic goods

Column 1 Item	Column 2 Circumstances	Column 3 Dosage form	Column 4 Route of administration	Column 5 Indication
1	(a) cannabidiol comprises 98% or more of the total cannabinoid content of the medicine; and (b) any cannabinoids, other than cannabidiol, in the medicine are only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the medicine; and (c) the medicine contains no other active ingredients	liquid	oral	(a) treatment of refractory chronic pain in adult patients; or (b) treatment of refractory anxiety in adult patients
2	(a) cannabidiol comprises 98% or more of the total cannabinoid content of the medicine; and (b) any cannabinoids, other than cannabidiol, in the medicine are only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the medicine; and (c) the medicine contains no other active ingredients	capsule	oral	(a) treatment of refractory chronic pain in adult patients; or (b) treatment of refractory anxiety in adult patients
3	(a) cannabidiol derived from cannabis comprises 60% or more and less than 98% of the total cannabinoid content of the medicine; and (b) other cannabinoids	liquid	oral	(a) treatment of refractory chronic pain in adult patients; or (b) treatment of refractory anxiety in adult patients

Regulation 12B

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Circumstances**	**Dosage form**	**Route of administration**	**Indication**
	(including tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content of the medicine; and (c) the medicine contains no other active ingredients			
4	(a) cannabidiol derived from cannabis comprises 60% or more and less than 98% of the total cannabinoid content of the medicine; and (b) other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content of the medicine; and (c) the medicine contains no other active ingredients	capsule	oral	(a) treatment of refractory chronic pain in adult patients; or (b) treatment of refractory anxiety in adult patients
5	(a) cannabidiol derived from cannabis comprises 40% or more and less than 60% of the total cannabinoid content of the medicine; and (b) other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content of the medicine; and (c) the medicine contains no other active ingredients	liquid	oral	treatment of refractory chronic pain in adult patients
6	(a) cannabidiol derived from cannabis comprises 40% or more	capsule	oral	treatment of refractory chronic pain in adult patients

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Circumstances**	**Dosage form**	**Route of administration**	**Indication**
	and less than 60% of the total cannabinoid content of the medicine; and (b) other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content of the medicine; and (c) the medicine contains no other active ingredients			

(2) The class of recipients prescribed for the purposes of paragraph 19(6)(b) of the Act is the class of recipients consisting of persons each of whom is suffering from a life-threatening, or otherwise serious, illness or condition.

(3) For the purposes of subsection 19(7) of the Act, the prescribed circumstances in which a medicine, or a class of medicines, may be supplied in accordance with an authority under subsection 19(5) of the Act are that the supplier of the medicine or class of medicines complies with the treatment directions (if any) mentioned in the authority for the medicine or class of medicine.

(5) For the purposes of paragraph 19(7B)(b) of the Act, rules made under subsection 19(7A) of the Act must not specify a medicine or a class of medicines if the medicine, or a medicine included in the class, contains a substance of a kind covered by an entry in Schedule 8, 9 or 10 to the Poisons Standard.

(6) For the purposes of paragraph 19(7D)(b) of the Act, the information that must be contained in a notification under subsection 19(7C) of the Act in relation to the supply by a health practitioner of a medicine to a person is as follows:

(a) the person's initials, date of birth and gender;
(b) each medical condition in relation to which the medicine was supplied;
(c) each indication of the medicine in relation to which the medicine was supplied;
(d) each active ingredient of the medicine;
(e) the dosage form of the medicine;
(f) if the release mechanism of the medicine was clinically relevant to the supply of the medicine—information about the release mechanism;
(g) if the route of administration of the medicine was clinically relevant to the supply of the medicine—information about the route of administration;
(h) the practitioner's name, AHPRA number and contact details;

(i) the health profession in which the practitioner is registered or licensed to practise;
(j) the address of the practitioner's principal place of practice.

12C Exemptions for health practitioners—biologicals

(1) For paragraph 32CM(4)(a) of the Act, the class of medical practitioners engaged in clinical practice in or outside a hospital is prescribed.

(2) For subsection 32CM(4) of the Act, paragraph 32CM(4)(b) does not apply to a medical practitioner engaged in clinical practice outside a hospital if the medical practitioner:
(a) has demonstrated that, for the proposed supply of the biological, the medical practitioner does not have access to an ethics committee that could approve the supply; and
(b) has received an endorsement, from a specialist college with established expertise relevant to the use of the biological, to supply the biological.

(3) For subsection 32CM(5) of the Act, the class of recipients each of whom is suffering from a life-threatening, or serious, illness or condition is prescribed.

(4) For subsection 32CM(6) of the Act, the circumstances are that the supplier of the biological complies with any treatment directions mentioned in the authority for the biological.

(5) For the purposes of paragraph 32CM(7D)(b) of the Act, the information that must be contained in a notification under subsection 32CM(7C) of the Act in relation to the supply by a health practitioner of a biological to a person is as follows:
(a) the person's initials, date of birth and gender;
(b) each medical condition in relation to which the biological was supplied;
(c) each indication of the biological in relation to which the biological was supplied;
(d) a description of the biological, including the following:
(i) the product name of the biological;
(ii) each active ingredient of the biological;
(iii) the route of administration of the biological;
(e) the practitioner's name, AHPRA number and contact details;
(f) the health profession in which the practitioner is registered or licensed to practise;
(g) the address of the practitioner's principal place of practice.

15 Application of registration or listing number to goods

(1) For the purposes of paragraphs 19D(3)(c) and (4)(c) of the Act, the registration number or listing number of therapeutic goods is to be set out on the label of the goods in the following manner:

(b) in the case of medicines—by writing the number on the label on the container of the medicines, or, if the container is enclosed in a primary pack for supply, on the label on that primary pack; and

(c) subject to subregulation (2), in each case—by writing the number on the main label, or on a securely affixed sticker adjacent to the main label, immediately preceded by:

(i) "AUST R" in the case of registered goods; and

(ii) unless subparagraph (iii) applies—"AUST L" in the case of listed goods; and

(iii) "AUST L(A)" in the case of goods listed under section 26AE of the Act;

the numbers and letters in each case being not less than 1 millimetre in height.

(2) If the Secretary is satisfied that compliance with paragraph (1)(c) in a particular case is not practicable, he or she may give a direction in writing that states an alternative manner in which the relevant number, immediately preceded by the appropriate letters stated in subparagraphs (1)(c)(i), (ii) or (iii), is to be set out, and in that case the number and letters are to be set out in accordance with the direction.

15AA Clinical trial registries

For the purposes of subparagraph 26AF(2)(b)(ii) of the Act, the following registries are prescribed:

(a) a primary registry that at any time is in the World Health Organisation's International Clinical Trials Registry Platform, as the registry exists from time to time;

(b) the database known as ClinicalTrials.gov, as the database exists from time to time.

15A Conditions of registration and listing of medicines

For the purposes of paragraphs 28(5)(ca) and (e) of the Act, a person in relation to whom a medicine is registered or listed must comply with the record-keeping requirements (if any) and the reporting requirements (if any) set out in the document published by the Therapeutic Goods Administration titled *Pharmacovigilance Responsibilities of Medicine Sponsors*, as in force from time to time.

16AA Information or documents that Secretary may require

Information or documents relating to registered goods

(1) For paragraph 31(1)(k) of the Act, the following matters are prescribed:

(a) matters relating to the scheme provided in Subdivision 2 of Division 1 of Part 7 of these Regulations for exempting a person from liability to pay an

annual registration charge in respect of the goods for a financial year, based on low value turnover of the goods;

(b) matters relating to an application to the Secretary under regulation 43AAH to waive the annual registration charge in respect of the goods for a financial year.

Information or documents relating to listed goods

(2) For paragraph 31(2)(h) of the Act, the following matters are prescribed:

(a) the efficacy of the goods for the purposes for which the goods are to be used;

(b) matters relating to the scheme provided in Subdivision 2 of Division 1 of Part 7 of these Regulations for exempting a person from liability to pay an annual listing charge in respect of the goods for a financial year, based on low value turnover of the goods;

(c) matters relating to an application to the Secretary under regulation 43AAH to waive the annual listing charge in respect of the goods for a financial year.

Information or documents relating to biologicals

(3) For paragraph 32JA(1)(p) of the Act, the following matters are prescribed:

(a) matters relating to the scheme provided in Subdivision 2 of Division 1 of Part 7 of these Regulations for exempting a person from liability to pay an annual charge for inclusion of the biological in the Register for a financial year, based on low value turnover of the biological;

(b) matters relating to an application to the Secretary under regulation 43AAH to waive the annual charge for inclusion of the biological in the Register for a financial year.

16AB Specified periods

For paragraphs 32DQ(1)(c) and (2)(c) of the Act and item 13 of the table in Schedule 5A to these Regulations, the period is as follows:

(a) if the information relates to an event or occurrence that represents a serious threat to public health—within 48 hours after the person first becomes aware of the event or occurrence;

(b) if the information relates to an event or occurrence that led to the death, or serious deterioration in the state of health of a patient, a user of the relevant biological or other goods or another person—within 10 days after the person first becomes aware of the event or occurrence;

(c) if the information relates to an event or occurrence that, if it occurred again, might lead to the death, or serious deterioration in the state of health, of a patient, a user of the relevant biological or other goods or another person—within 30 days after the person first becomes aware of the event or occurrence.

Part 3A—Applications for evaluation

Division 1—Preliminary

16A Interpretation—*working day*

(1) In this Part, ***working day*** means a day that is not a Saturday, a Sunday or a day that is a holiday for Commonwealth offices in the Australian Capital Territory.

(2) The following periods are to be disregarded in calculating, for the purposes of a provision of this Part, the number of working days taken to perform the action that the provision requires to be performed:

(a) the period commencing on the day on which the Secretary sends a query, or a request for information, to an applicant or sponsor and ending either:

(i) at the end of the day on which the Secretary receives from the applicant or sponsor a complete response to the query or request; or

(ii) if subsection 31(1B) or (1C) of the Act applies:

(A) at the end of the last day in the period specified in the notice given by the Secretary under subsection 31(1) of the Act; or

(B) if the applicant or sponsor and the Secretary agree in writing on another day for the purposes of this sub-subparagraph—that day.

(b) the period commencing on the day of lodgment of an appeal concerning the application for which the action is required to be performed and ending at the end of the day on which the appeal is finally disposed of; and

(c) any other period to which the applicant or sponsor agrees in writing for the purposes of this subregulation.

Division 1A—Goods mentioned in Part 1 of Schedule 10

16C Applications for registration—notification of effectiveness and period for completing evaluations—general

Application of this regulation

(1) This regulation applies if the Secretary receives an application:
  (a) made under section 23 of the Act for the registration of a medicine that is a product of a kind specified in Part 1 of Schedule 10 to these Regulations; and
  (b) to which regulation 16G does not apply.

Giving notification whether application has passed preliminary assessment

(2) For the purposes of paragraph 63(2)(de) of the Act, the Secretary must, within 40 working days from the day of receipt of the application, send a notification in writing to the applicant that states whether the application has passed preliminary assessment.

Period for completing evaluation in relation to application

(3) For the purposes of paragraph 63(2)(da) of the Act, if section 25 of the Act requires an evaluation in relation to the application, the evaluation must be completed within the period of:
  (a) if the conditions mentioned in subregulations 16DA(1) and (2) are satisfied—120 working days; or
  (b) if the conditions mentioned in subregulation 16DA(1) are satisfied, but a condition mentioned in subregulation 16DA(2) is not satisfied—175 working days; or
  (c) otherwise—255 working days;

beginning on the day the Secretary sends the notification that states that the application has passed preliminary assessment.

16D Applications for variations—notification of effectiveness and period for deciding applications—general

Application of this regulation

(1) This regulation applies if the Secretary receives an application:
  (a) made under subsection 9D(3) of the Act to vary information included in an entry in the Register that relates to a medicine that is a product of a kind specified in Part 1 of Schedule 10 to these Regulations; and
  (b) to which regulation 16F does not apply.

Giving notification of effectiveness of application

(2) The Secretary must, within 40 working days from the day of receipt of the application, send a notification in writing to the applicant that states whether the application is effective.

Period for completing evaluation in relation to application

(3) For the purposes of paragraph 63(2)(df) of the Act, if the application is effective, the application must be decided, and the applicant must be given notification of the decision, within the period of:

(a) if, in respect of the evaluation in relation to the application, the conditions mentioned in subregulations 16DA(1) and (2) are satisfied—120 working days; or

(b) if, in respect of the evaluation in relation to the application, the conditions mentioned in subregulation 16DA(1) are satisfied, but a condition mentioned in subregulation16DA(2) is not satisfied—175 working days; or

(c) otherwise—255 working days;

beginning on the day the Secretary sends the notification that states that the application is effective.

16DA Conditions for periods for regulations 16C and 16D

Conditions for 175 day period

(1) For the purposes of paragraphs 16C(3)(a) and (b) and 16D(3)(a) and (b), the conditions are the following:

(a) the evaluation relates to a medicine (the ***evaluation medicine***) that is the same as a medicine (an ***acceptable foreign approved medicine***) that has been approved by a competent regulatory authority, of a foreign country or foreign jurisdiction determined under subregulation (3), for general marketing in that country or jurisdiction;

(c) the indications of the evaluation medicine are equivalent to the indications of the acceptable foreign approved medicine;

(d) the strength, dosage form, formulation and directions for use of the evaluation medicine are identical to those of the acceptable foreign approved medicine;

(e) the manufacturer and manufacturing process for the evaluation medicine are identical to those for the acceptable foreign approved medicine;

(f) an application for marketing approval for the evaluation medicine has not been delayed, deferred, rejected, refused or withdrawn in any country;

(g) if the evaluation medicine is a generic product in comparison to a registered medicine:

(i) the indications of the evaluation medicine are identical to the indications of the registered medicine; and

(ii) the reference product used by the competent regulatory authority mentioned in paragraph (a) to assess the bioequivalence of the acceptable foreign approved medicine (in assessing the application for

the approval for the acceptable foreign approved medicine) is identical to the registered medicine;

(h) if the evaluation medicine is a biosimilar in relation to a registered medicine—the reference product used by the competent regulatory authority mentioned in paragraph (a) (in assessing the application for the approval for the acceptable foreign approved medicine) is identical to the registered medicine;

(i) the applicant in relation to the evaluation has given the Secretary the assessment, by the competent regulatory authority mentioned in paragraph (a), of the application for the approval for the acceptable foreign approved medicine;

(j) the assessment mentioned in paragraph (i):

(i) is complete and unredacted; and

(ii) is in English; and

(iii) includes comprehensive details of studies assessed in connection with the application for the approval for the acceptable foreign approved medicine; and

(iv) includes copies of any correspondence relating to the application for the approval for the acceptable foreign approved medicine between the competent regulatory authority and the applicant for the approval; and

(v) includes the competent regulatory authority's final decision; and

(vi) includes any certifications or authentications of reports relating to the approval; and

(vii) is not, wholly or in part, based on (including compiled by reference to or in reliance on) any other assessment or evaluation (however described).

Conditions for 120 day period

(2) For the purposes of paragraphs 16C(3)(a) and (b) and 16D(3)(a) and (b), the conditions are the following:

(aa) the approval for the acceptable foreign approved medicine:

(i) is in force; and

(ii) was given not more than 12 months before the date of the application in relation to the evaluation;

(a) the manufacturing site at which manufacturing steps other than labelling and release for supply are carried out for the evaluation medicine is identical to that for the acceptable foreign approved medicine;

(b) if the evaluation medicine is manufactured in Australia—there is evidence that the medicine has been manufactured in accordance with Part 3-3 of the Act;

(c) if a step in the manufacture of the evaluation medicine has been carried out outside Australia—there is evidence that the manufacturing and quality control procedures used in the manufacture of the medicine are acceptable;

(d) no additional information is required to complete the evaluation, other than:

(i) the label and product information for the evaluation medicine; and
(ii) the risk management plan (if any) for the evaluation medicine.

Determining foreign countries or foreign jurisdictions

(3) The Secretary may, in writing published on the Therapeutic Goods Administration website, determine a foreign country or a foreign jurisdiction for the purposes of this regulation.

16E Applications for variations—effect of failure to decide applications within specified period

The failure to decide, within the period specified in subregulation 16D(3), an application to which regulation 16D applies does not make the Commonwealth, the Secretary or a delegate of the Secretary liable to a person for loss, damage or injury, of any kind, that is caused by or arises out of the failure.

16F Applications for variations—shorter period for deciding applications

(1) Subject to subregulation (2), this regulation applies to an application, in relation to a medicine included in the Register that is a product of a kind specified in Part 1 of Schedule 10, to vary the information in the Register concerning the medicine in relation to:
(a) the specifications for the active ingredient, finished product or excipients; or
(b) the method of manufacture of the active ingredient; or
(c) the manufacturing procedure for the finished product; or
(d) the site of manufacture of the active ingredient or the finished product; or
(e) the shelf life; or
(f) the storage conditions; or
(g) the labelling; or
(h) any other particular that is not a particular mentioned in subsection 16(1) of the Act.

(2) This regulation does not apply to an application that:
(a) in the opinion of the Secretary, needs to be supported by clinical, pre-clinical or bio-equivalence data; or
(b) applies for a variation of therapeutic goods that will make the therapeutic goods as varied separate and distinct therapeutic goods because of subsection 16(1) of the Act.

(3) In the case of an application to which this regulation applies, the Secretary must:
(a) decide the application and notify the applicant of the decision; or
(b) raise an objection concerning the application;
within the period of 45 working days that commences on the day on which the application is lodged and the evaluation fee for the application is paid or, if lodgment and payment occur on different days, on the later of those days.

(4) If the Secretary raises an objection concerning an application to which this regulation applies, he or she must decide the application and notify the applicant of the decision within the period of 30 working days that commences on the day on which the Secretary receives the applicant's response to the objection.

(5) If the Secretary does not comply with subregulation (3) and, if applicable, subregulation (4) in the case of an application to which this regulation applies, the Secretary is taken to have approved the application.

16G Applications for registration—shorter period for completing evaluations

(1) Subject to subregulation (2), this regulation applies to an application to register a medicine that is a product of a kind specified in Part 1 of Schedule 10 if:
  (a) the application is received by the Secretary on or after 1 July 1992; and
  (b) the application requires an evaluation under section 25 of the Act; and
  (c) the sponsor of the application holds a registration for a medicine that contains the same active ingredient or active ingredients, in the same dosage form and strength as stated in the application.

(2) This regulation does not apply to an application that, in the opinion of the Secretary, needs to be supported by clinical, pre-clinical or bio-equivalence data.

(3) The provisions of subregulations 16F(3), (4) and (5) apply to applications to which this regulation applies as if those applications were applications to which regulation 16F applies.

Division 2—Applications for evaluation of substances

16GA Evaluation other than evaluation under subsection 9D(1), (2) or (3) or section 25 of the Act

(1) At the request of a person, and on payment of the prescribed fee, the Department may evaluate data submitted by the person concerning the following substances:

(a) a substance that is not an ingredient in listed goods or registered goods for supply in Australia, but that may be an ingredient in goods for which an application may be made for entry in the Register as listed goods or registered goods for supply in Australia;

(b) a new excipient in therapeutic goods for dermal application, being a substance not in use as an ingredient in any other listed goods or registered goods for supply in Australia at the time of conditional listing or conditional registration of those goods under section 28 of the Act.

(2) An evaluation under this regulation may be made, although an application under subsection 9D(1), (2) or (3) or section 23 of the Act is not current.

Exemption from fee

(3) No fee is payable for an evaluation under paragraph (1)(b) if the evaluation is in respect of a new excipient introduced for use as an ingredient, in compliance with a condition under section 28 of the Act, imposed before the commencement of this regulation but not earlier than 6 months before the application for evaluation is made.

Division 3—Class 2, Class 3 and Class 4 biologicals

16GC Notification of preliminary assessment of applications and periods within which certain evaluations must be made

(1) This regulation applies to an application under section 32DD of the Act that requires an evaluation of a Class 2, Class 3 or Class 4 biological under section 32DE of the Act.

(2) For the purposes of paragraph 63(2)(de) of the Act, the Secretary must send a notification in writing to the applicant that states whether the application has passed preliminary assessment within 30 working days after the Secretary receives the application.

(3) For the purposes of paragraph 63(2)(da) of the Act, the evaluation must be completed within 255 working days after the Secretary sends a notification to the applicant under subregulation (2).

16GD Notification of effective request and period within which certain applications must be decided

(1) This regulation applies to an application (other than an application to which regulation 16GF applies) for an evaluation of a biological if the application requests the Secretary under subsection 9D(3A) or (3AA) of the Act to vary the entry of the Class 2, Class 3 or Class 4 biological in the Register.

(2) For the purposes of paragraph 63(2)(de) of the Act, the Secretary must send a notification in writing to the applicant that states whether the application is effective within 30 working days after the Secretary receives the application.

(3) For the purposes of paragraph 63(2)(df) of the Act, the application must be decided, and notification given to the applicant, within 255 working days after the Secretary sends a notification to the applicant under subregulation (2) that the application is effective.

16GE Failure to decide an application within specified time

The failure to decide, within the time mentioned in subregulation 16GD(3), an application to which regulation 16GD applies does not make the Commonwealth, the Secretary or a delegate of the Secretary liable to a person for loss, damage or injury, of any kind, that is caused by or arises out of the failure.

16GF Evaluation, other than evaluation under subsection 9D(3A) or (3AA) or section 32DE of the Act

(1) At the request of a person, and on payment of the prescribed fee, the Department may evaluate data submitted by the person about the following substances:

(a) a substance that is not an ingredient in a biological for supply in Australia, but that may be an ingredient in a biological for which an application may

be made for inclusion in the Register under Part 3-2A of the Act as a biological for supply in Australia;

(b) a new excipient in a biological, being a substance not in use as an ingredient in any other biological for supply in Australia at the time of inclusion in the Register under Part 3-2A of the Act.

(2) An evaluation under this regulation may be made, although an application under subsection 9D(3A) or (3AA) or section 32DD of the Act is not current.

Division 4—Complementary medicines and certain other listed medicines

16GG Variation of certain entries in the Register—notification of effective requests and period within which decisions must be made

(1) For the purposes of paragraph 63(2)(df) of the Act, if the Secretary receives an RCMC1 (section 9D) request, a decision on the request must be made within 20 working days after the Secretary receives the application.

(2) If the Secretary receives a request of a kind mentioned in column 1 of an item in the following table:

(a) the Secretary must notify the person making the request in writing as to whether the request is effective within the period specified, for the purposes of paragraph 63(2)(de) of the Act, in column 2 of the item; and

(b) if the request is effective—a decision on the request must be made within the period specified, for the purposes of paragraph 63(2)(df) of the Act, in column 3 of the item.

Notification of effective requests and period within which decisions must be made

Item	Column 1 Kind of request	Column 2 Notification of effective requests	Column 3 Decision on request
1A	L(A)C1 (section 9D) request	Within 40 working days after the Secretary receives the request	Within 30 working days after the Secretary notifies the applicant that the request has been accepted
1B	L(A)C2 (section 9D) request	Within 40 working days after the Secretary receives the request	Within 120 working days after the Secretary notifies the applicant that the request has been accepted
1	RCMC2 (section 9D) request	Within 40 working days after the Secretary receives the request	Within 64 working days after the Secretary notifies the applicant that the request has been accepted
2	RCMC3 (section 9D) request	Within 40 working days after the Secretary receives the application	Within 120 working days after the Secretary notifies the applicant that the request has been accepted
3	RCMC4 (section 9D) request	Within 40 working days after the Secretary receives the application	Within 170 working days after the Secretary notifies the applicant that the request has been accepted

(3) A failure to make a decision on a request mentioned in this regulation within the period mentioned in this regulation does not make the Commonwealth, the Secretary or a delegate of the Secretary liable to a person for loss, damage or injury, of any kind, that is caused by or arises out of the failure.

16GH Registration and listing of certain medicines—notification of preliminary assessment of applications and period within which evaluations must be completed

(1) If the Secretary receives an application of a kind mentioned in column 1 of an item in the following table:

(a) the Secretary must notify the applicant in writing as to whether the application has passed preliminary assessment within the period specified, for the purposes of paragraph 63(2)(de) of the Act, in column 2 of the item; and

(b) if the application passes preliminary assessment—the evaluation of the medicine to which the application relates must be completed within the period specified, for the purposes of paragraphs 63(2)(da) and (daaaa) of the Act, in column 3 of the item.

Notification of preliminary assessment of application and period within which evaluations must be completed

Item	Column 1 Kind of application	Column 2 Notification of preliminary assessment	Column 3 Completion of evaluation
1	L(A)1 application	Within 40 working days after the Secretary receives the application	Within 45 working days after the Secretary notifies the applicant that the application has passed preliminary assessment
2	L(A)2 application	Within 40 working days after the Secretary receives the application	Within 60 working days after the Secretary notifies the applicant that the application has passed preliminary assessment
3	L(A)3 application	Within 40 working days after the Secretary receives the application	Within 150 working days after the Secretary notifies the applicant that the application has passed preliminary assessment
3A	L(A)C1 (section 23) application	Within 40 working days after the Secretary receives the application	Within 30 working days after the Secretary notifies the applicant that the application has passed preliminary assessment
3B	L(A)C2 (section 23) application	Within 40 working days after the Secretary receives the application	Within 120 working days after the Secretary notifies the applicant that the application has passed preliminary assessment
4	RCM1 application	Within 40 working days after the Secretary receives the application	Within 45 working days after the Secretary notifies the applicant that the application has passed preliminary assessment
5	RCM2 application	Within 40 working days after the Secretary receives the application	Within 90 working days after the Secretary notifies the applicant that the application has passed preliminary assessment
6	RCM3 application	Within 40 working days after the Secretary receives the application	Within 150 working days after the Secretary notifies the applicant that the application has passed preliminary assessment
7	RCM4 application	Within 40 working days after the Secretary receives the application	Within 180 working days after the Secretary notifies the applicant that the application has passed preliminary assessment

Notification of preliminary assessment of application and period within which evaluations must be completed			
Item	**Column 1** **Kind of application**	**Column 2** **Notification of preliminary assessment**	**Column 3** **Completion of evaluation**
8	RCM5 application	Within 40 working days after the Secretary receives the application	Within 210 working days after the Secretary notifies the applicant that the application has passed preliminary assessment
9	RCMC1 (section 23) application	Within 40 working days after the Secretary receives the application	Within 20 working days after the Secretary notifies the applicant that the application has passed preliminary assessment
10	RCMC2 (section 23) application	Within 40 working days after the Secretary receives the application	Within 64 working days after the Secretary notifies the applicant that the application has passed preliminary assessment
11	RCMC3 (section 23) application	Within 40 working days after the Secretary receives the application	Within 120 working days after the Secretary notifies the applicant that the application has passed preliminary assessment
12	RCMC4 (section 23) application	Within 40 working days after the Secretary receives the application	Within 170 working days after the Secretary notifies the applicant that the application has passed preliminary assessment

(2) A failure to complete an evaluation of 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 does not make the Commonwealth, the Secretary or a delegate of the Secretary liable to a person for loss, damage or injury, of any kind, that is caused by or arises out of the failure.

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

(1) If the Secretary receives an application of a kind mentioned in column 1 of an item in the following table:

(a) the Secretary must notify the applicant in writing as to whether the application has passed preliminary assessment within the period specified, for the purposes of paragraph 63(2)(de) of the Act, in column 2 of the item; and

(b) if the application passes preliminary assessment—subject to subregulation (1A), a decision on whether to make a recommendation on the application must be made within the period specified, for the purposes of paragraph 63(2)(daaa) of the Act, in column 3 of the item.

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 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

(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.

(2) A failure to make a decision on whether to make a recommendation on an application within the period applicable under this regulation does not make the Commonwealth, the Secretary or a delegate of the Secretary liable to a person for loss, damage or injury, of any kind, that is caused by or arises out of the failure.

16GIA Period for paying evaluation fee for application under subsection 26BD(1) of the Act

For the purposes of paragraph 26BDA(c) of the Act, the period is the period of 2 months beginning on the day that the applicant is notified of the amount of the evaluation fee and of the requirement for that fee to be paid.

16GJ Determination of competent regulatory authority of a foreign country or foreign jurisdiction in relation to evaluation of applications

The Secretary may, in writing published on the Therapeutic Goods Administration website, determine a competent regulatory authority of a foreign country or a foreign jurisdiction in relation to the evaluation of the following medicine applications:

(a) an IN1 application;

(b) an IN2 application;
(c) an IN3 application;
(d) an L(A)2 application;
(e) an RCM2 application;
(f) an RCM3 application;
(g) an RCM4 application.

Part 3B—Designated orphan drugs

16H Application to designate medicine as orphan drug

(1) The sponsor of a medicine may apply to the Secretary to designate, in writing, the medicine as an orphan drug.

(2) An application under subregulation (1) must be in a form approved, in writing, by the Secretary.

16J Designation of medicine as orphan drug

(1) On receiving an application under subregulation 16H(1) to designate a medicine as an orphan drug, the Secretary must:
  (a) consider the application; and
  (b) decide either:
    (i) to designate the medicine as an orphan drug; or
    (ii) to refuse to designate the medicine as an orphan drug.

(2) The Secretary may decide to designate the medicine as an orphan drug if the Secretary is satisfied, having regard to any matter that the Secretary considers relevant, that:
  (a) if the medicine is not a new dosage form medicine—all of the criteria specified in subregulation (3) are satisfied in relation to the medicine; or
  (b) if the medicine is a new dosage form medicine—all of the criteria specified in subregulation (4) are satisfied in relation to the medicine.

General criteria

(3) The following criteria are specified in relation to a medicine that is not a new dosage form medicine:
  (a) the application is for only one indication of the medicine;
  (b) the indication is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition in a particular class of patients (the ***relevant patient class***);
  (c) it is not medically plausible that the medicine could effectively treat, prevent or diagnose the condition in another class of patients that is not covered by the relevant patient class;
  (d) at least one of the following applies:
    (i) if the medicine is intended to treat the condition—the condition affects fewer than 5 in 10,000 individuals in Australia when the application is made;
    (ii) if the medicine is intended to prevent or diagnose the condition—the medicine, if it were included in the Register, would not be likely to be supplied to more than 5 in 10,000 individuals in Australia during each year that it is included in the Register;

(iii) it is not likely to be financially viable for the sponsor to market the medicine in Australia unless each fee referred to in paragraph 45(12)(c) were waived in relation to the medicine;

(e) none of the following has refused to approve the medicine for the treatment, prevention or diagnosis of the condition for a reason relating to the medicine's safety:

(i) the Secretary;

(ii) the United States Food and Drug Administration;

(iii) the European Medicines Agency;

(iv) Health Canada;

(v) the Medicines and Healthcare products Regulatory Agency of the United Kingdom;

(f) either:

(i) no therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods); or

(ii) if one or more therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods)—the medicine provides a significant benefit in relation to the efficacy or safety of the treatment, prevention or diagnosis of the condition, or a major contribution to patient care, compared to those goods.

New dosage form medicines

(4) The following criteria are specified in relation to a new dosage form medicine:

(a) the application is for only one indication of the medicine;

(b) the indication is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition;

(c) it is not likely to be financially viable for the sponsor to market the medicine in Australia unless each fee referred to in paragraph 45(12)(c) were waived in relation to the medicine;

(d) none of the following has refused to approve the medicine for the treatment, prevention or diagnosis of the condition for a reason relating to the medicine's safety:

(i) the Secretary;

(ii) the United States Food and Drug Administration;

(iii) the European Medicines Agency;

(iv) Health Canada;

(v) the Medicines and Healthcare products Regulatory Agency of the United Kingdom;

(e) either:

(i) no therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods); or

(ii) if one or more therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods)—the medicine provides a significant benefit in relation to the efficacy or safety of the treatment, prevention or diagnosis of the condition, or a major contribution to patient care, compared to those goods.

Publication of decision

(5) If the Secretary decides to designate the medicine as an orphan drug, the Secretary must, as soon as practicable after making the decision, publish a notice on the Department's website stating the following:

(a) the name of the sponsor of the medicine;

(b) the indication referred to in paragraph (3)(a) or (4)(a);

(c) the dosage form of the medicine;

(d) that the medicine is a designated orphan drug.

Notification of decision

(6) As soon as practicable after making the decision, the Secretary must notify the applicant, in writing, of the decision.

(7) If the Secretary decides to refuse to make the designation, the notification must include the reasons for the decision.

16K Period during which designation is in force

(1) A designation under regulation 16J of a medicine as an orphan drug:

(a) comes into force when it is made; and

(b) remains in force for a period of 6 months.

(2) Subregulation (1) has effect subject to regulations 16L and 16M.

16L Extension of designation

(1) If a designation under regulation 16J of a medicine as an orphan drug is in force, the sponsor of the medicine may apply to the Secretary to extend the designation for a further 6 months.

(2) An application under subregulation (1) to extend a designation must:

(a) be in a form approved, in writing, by the Secretary; and

(b) be made at least 28 days before the designation would cease to be in force.

(3) On receiving an application under subregulation (1) to extend a designation, the Secretary must decide either:

(a) to extend the designation; or

(b) to refuse to extend the designation.

(4) The Secretary may extend the designation if:

(a) the Secretary has not previously extended the designation; and

(b) the Secretary is satisfied that:

(i) if the medicine is not a new dosage form medicine—the criteria specified in paragraphs 16J(3)(e) and (f) are satisfied in relation to the medicine; or

(ii) if the medicine is a new dosage form medicine—the criteria specified in paragraphs 16J(4)(d) and (e) are satisfied in relation to the medicine; and

(c) the Secretary is satisfied that, if the Secretary were to extend the designation, the sponsor would make an application in relation to the medicine under section 23 of the Act before the end of the extended designation.

Notification of decision

(5) As soon as practicable after making the decision, the Secretary must notify the applicant, in writing, of the decision.

(6) If the Secretary decides to refuse to extend the designation, the notification must include the reasons for the decision.

16M Revocation of designation

(1) The Secretary may, by written notice given to the sponsor of a designated orphan drug, revoke the designation:

(a) on application by the sponsor; or

(b) if the Secretary is satisfied that:

(i) if the designated orphan drug is a new dosage form medicine—the criteria specified in subregulation 16J(4) are no longer satisfied in relation to the designated orphan drug; or

(ii) if the designated orphan drug is not a new dosage form medicine—the criteria specified in subregulation 16J(3) are no longer satisfied in relation to the designated orphan drug.

(2) Subsection 33(3) of the *Acts Interpretation Act 1901* does not apply in relation to a revocation of a designation under regulation 16J of a medicine as an orphan drug.

Part 3C—Therapeutic goods (priority applicant) determinations

16P Application of Part

For the purposes of subsection 25AAA(1) of the Act, this Part makes provision for and in relation to the making of a therapeutic goods (priority applicant) determination in relation to a medicine.

16Q Application for therapeutic goods (priority applicant) determination

(1) A person may apply to the Secretary for a therapeutic goods (priority applicant) determination in relation to a medicine.

(2) An application under subregulation (1) must:
  (a) be in writing; and
  (b) be in a form approved, in writing, by the Secretary; and
  (c) have with it written information in such detail as is reasonably necessary to allow the application to be properly considered.

(3) An application under subregulation (1) is taken not to have been made unless:
  (a) the application meets the requirements in subregulation (2); and
  (b) subject to paragraph 45(12)(d), the fee prescribed in item 1B of Part 2 of Schedule 9 for making the application has been paid.

Note: Paragraph 45(12)(d) provides that the Secretary must waive the fee for applying for a therapeutic goods (priority applicant) determination in certain circumstances.

16R Making of therapeutic goods (priority applicant) determination

(1) On receiving an application under subregulation 16Q(1) for a therapeutic goods (priority applicant) determination in relation to a medicine, the Secretary must:
  (a) consider the application; and
  (b) decide either:
    (i) to make the determination; or
    (ii) to refuse to make the determination.

Criteria

(2) The Secretary may make the determination if the Secretary is satisfied, having regard to any matter that the Secretary considers relevant, that all of the following criteria are satisfied in relation to the medicine:
  (a) the medicine is:
    (i) a new prescription medicine; or
    (ii) a new indications medicine;

(b) an indication of the medicine (the ***priority indication***) is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition;

(c) either:

(i) no therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods); or

(ii) if one or more therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods)—there is substantial evidence demonstrating that the medicine provides a significant improvement in the efficacy or safety of the treatment, prevention or diagnosis of the condition compared to those goods;

(d) there is substantial evidence demonstrating that the medicine provides a major therapeutic advance.

Note: Paragraph 16(1)(e) of the Act provides that, for the purposes of Part 3-2 of the Act, therapeutic goods (other than medicine of the kind to which subsection 16(1A) of the Act applies) are to be taken to be separate and distinct from other therapeutic goods if they have different indications.

Information to be specified in determination

(3) The determination must specify:

(a) the person who, as a result of section 25AAA of the Act, is the priority applicant; and

(b) each active ingredient of the medicine to which the determination relates; and

(c) the priority indication of the medicine.

Notification of decision

(4) As soon as practicable after making the decision, the Secretary must notify the applicant, in writing, of the decision.

(5) If the Secretary decides to refuse to make the determination, the notification must include the reasons for the decision.

16S Period during which therapeutic goods (priority applicant) determination is in force

(1) A therapeutic goods (priority applicant) determination in relation to a medicine:

(a) comes into force on the day on which the Secretary notifies the priority applicant in accordance with subregulation 16R(4); and

(b) subject to subregulation (2) and regulation 16T, remains in force for 6 months.

(2) If the priority applicant specified in the determination makes an application under section 23 of the Act for the registration of the medicine that passes

preliminary assessment before the end of the 6 month period beginning when the determination comes into force, the determination remains in force until:

(a) the priority applicant withdraws the application; or

(b) the application lapses in accordance with subsection 24(2) of the Act; or

(c) the priority applicant gives the Secretary written notice under subsection 24E(2) of the Act that the applicant wishes to treat the application as having been refused; or

(d) the application is finally determined.

Note: See subsection 23B(3) of the Act for when an application passes preliminary assessment.

16T Revocation of therapeutic goods (priority applicant) determination

(1) The Secretary may revoke a therapeutic goods (priority applicant) determination in relation to a medicine if:

(a) either:

(i) the priority applicant specified in the determination has not made an application under section 23 of the Act for the registration of the medicine; or

(ii) the priority applicant has made such an application, but the application does not pass preliminary assessment; and

(b) the Secretary is satisfied that the criteria specified in subregulation 16R(2) are no longer satisfied in relation to the medicine.

Note: See subsection 23B(3) of the Act for when an application passes preliminary assessment.

(2) The revocation must be by written notice given by the Secretary to the priority applicant.

Part 3D—Biologicals (priority applicant) determinations

16U Application of Part

For the purposes of subsection 32DEA(1) of the Act, this Part makes provision for and in relation to the making of biologicals (priority applicant) determinations.

16V Application for biologicals (priority applicant) determination

(1) A person may apply to the Secretary for a biologicals (priority applicant) determination in relation to a biological, other than a Class 1 biological or an export only biological.

(2) An application under subregulation (1) must:
  (a) be in writing; and
  (b) be in a form approved, in writing, by the Secretary; and
  (c) have with it written information in such detail as is reasonably necessary to allow the application to be properly considered.

(3) An application under subregulation (1) is taken to not have been made unless:
  (a) the application meets the requirements in subregulation (2); and
  (b) the fee prescribed in item 2A in Part 2 of Schedule 9A for making the application has been paid.

16W Making of biologicals (priority applicant) determination

(1) On receiving an application under subregulation 16V(1) for a biologicals (priority applicant) determination in relation to a biological, the Secretary must:
  (a) consider the application; and
  (b) decide either:
    (i) to make the determination; or
    (ii) to refuse to make the determination.

Criteria

(2) The Secretary may make the determination if the Secretary is satisfied, having regard to any matter that the Secretary considers relevant, that all of the following criteria are satisfied in relation to the biological:
  (a) the biological is separate and distinct from biologicals included in the Register;
  (b) either:
    (i) for a Class 2 biological—an intended clinical use (the ***priority indication***) of the biological is the treatment, prevention or diagnosis of a life-threating or seriously debilitating condition; or

(ii) for a Class 3 or Class 4 biological—a therapeutic indication (the ***priority indication***) of the biological is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition;

(c) either:

(i) no therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods); or

(ii) if one or more therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods)—there is substantial evidence demonstrating that the biological provides a significant improvement in the efficacy or safety of the treatment, prevention or diagnosis of the condition compared to those goods;

(d) there is substantial evidence demonstrating that the biological provides a major therapeutic advance.

Note: For paragraph (a), see section 32AB of the Act and regulation 11A for when a biological is separate and distinct from other biologicals.

Information to be specified in the determination

(3) The determination must specify:

(a) the person who, as a result of section 32DEA of the Act, is the priority applicant; and

(b) each active ingredient of the biological to which the determination relates; and

(c) the priority indication of the biological.

Notification of decision

(4) As soon as practicable after making the decision, the Secretary must notify the applicant, in writing, of the decision.

(5) If the Secretary decides to refuse to make the determination, the notification must include the reasons for the decision.

16X Period during which biologicals (priority applicant) determination is in force

(1) A biologicals (priority applicant) determination in relation to a biological:

(a) comes into force on the day on which the Secretary notifies the priority applicant in accordance with subregulation 16W(4); and

(b) subject to subregulation (2) and regulation 16Y, remains in force for 6 months.

(2) If the priority applicant specified in the determination makes an application under section 32DD of the Act to include the biological in the Register that passes preliminary assessment before the end of the 6 month period beginning

when the determination comes into force, the determination remains in force until:

(a) the priority applicant withdraws the application; or

(b) the application lapses in accordance with section 32DH of the Act; or

(c) the application is finally determined.

Note: See subsection 32DDA(3) of the Act for when an application passes preliminary assessment.

16Y Revocation of biologicals (priority applicant) determination

(1) The Secretary may revoke a biologicals (priority applicant) determination in relation to a biological if:

(a) either:

(i) the priority applicant specified in the determination has not made an application under section 32DD of the Act to include the biological in the Register; or

(ii) the priority applicant has made such an application, but the application does not pass preliminary assessment; and

(b) the Secretary is satisfied that the criteria specified in subregulation 16W(2) are no longer satisfied in relation to the biological.

Note: See subsection 32DDA(3) of the Act for when an application passes preliminary assessment.

(2) The revocation must be by written notice given by the Secretary to the priority applicant.

Part 4—Licensing of manufacturers

17 Exempt goods for the purposes of subsection 34(1) of the Act

(1) For the purposes of subsection 34(1) of the Act, the therapeutic goods specified in Schedule 7 are exempt from the operation of Part 3-3 of the Act unless the goods are supplied as pharmaceutical benefits.

(2) If:

(a) therapeutic goods that are exempt from the operation of Part 3-3 of the Act cease to be exempt; and

(b) before the day on which the goods cease to be exempt, each person who carries out a step in the manufacture of the goods applies for a licence authorising the person to carry out the step on premises referred to in the application;

the goods produced by those persons carrying out the steps on those premises are taken to be exempt from the operation of that Part until each application is determined.

18 Exempt Persons

For the purposes of subsection 34(2) of the Act, the persons specified in column 2 of an item in Schedule 8 are exempt from the operation of Part 3-3 of the Act in relation to the manufacture, or the steps in the manufacture, of the therapeutic goods specified in column 3 of that item.

19 Requirements for licence holders

For the purposes of section 40 of the Act, it is a condition of each licence that the licence holder must give the Secretary, at the time of payment of the annual licensing charge in respect of the licence:

(a) if the Secretary so requests—details of therapeutic goods manufactured by or on behalf of the licence holder during the period of 12 months immediately preceding the date on which the payment of the charge is due; and

(b) the name, qualifications and details of the relevant experience of any person nominated by the licence holder as having control of:

(i) the production of the goods; and

(ii) the quality control measures that are to be employed in the manufacture of the goods.

20 Conditions of licences

For the purposes of section 40 of the Act, the following are conditions to which each licence is subject:

(a) a copy of the licence and of any document issued by the Secretary imposing or amending the conditions applicable to that licence are to be displayed publicly at the premises specified in the licence;

(b) unless the contrary intention appears in the licence or in documents issued by the Secretary imposing or amending the conditions applicable to the licence, the licence holder must:

(i) keep records showing:

(A) the materials used in the manufacture of the goods, the supplier and quantities of the materials used and details of the tests performed on those materials; and

(B) the procedures and controls employed in the manufacture of the goods, including the results of tests carried out during the processing of the goods; and

(C) details of the tests performed on the goods and the results of those tests; and

(D) the stability studies (if any) that validate the recommended shelf life and appropriate storage conditions of the goods; and

(ii) where the goods to which the licence relates are produced in identifiable batches:

(A) assign a batch number to each batch of the goods; and

(B) if it is not unreasonable in the circumstances—retain at those premises, for not less than 12 months after the expiry date of the goods or, if there is no expiry date, for not less than 6 years after completion of manufacture of the goods, a sample of each batch of the finished goods; and

(iii) retain those records at the licensed premises for at least 12 months after the expiry date of the goods to which they relate or, if there is no expiry date, for not less than 6 years after completion of manufacture of the goods; and

(iv) ensure that the persons nominated by the licence holder as having control of the production of the goods and of the quality control measures that are to be employed in the manufacture of the goods maintain that control;

(c) the licence holder must comply with the provisions of Part 5 in relation to the taking of samples by authorised officers.

21 Persons having control of production etc to be named

If:

(a) an applicant for a licence to manufacture therapeutic goods nominates a person as having control of the production of goods or the quality control measures in respect of the manufacture of the goods; and

(b) the licence is granted; and

(c) the applicant wishes to replace the nominated person with another person;

then it is a condition of the licence that the licence holder must inform the Secretary as soon as practicable of the name, qualifications and experience of that other person.

22 Transfer of licences

(1) If a person who was the holder of a licence dies, the legal personal representative of the dead person:

(a) is taken to be the holder of the licence; and

(b) must notify the Secretary, in writing, of the death not later than 3 months after it occurred.

(2) If a person who is the holder of a licence becomes bankrupt, the trustee in bankruptcy of the estate of the bankrupt:

(a) is taken to be the holder of the licence; and

(b) must notify the Secretary, in writing, of the bankruptcy not later than 3 months after the person became bankrupt.

(3) If a body corporate that is the holder of a licence is being wound up, the liquidator of the body corporate:

(a) is taken to be the holder of the licence; and

(b) must, not later than 3 months after the body corporate is wound up, notify the Secretary, in writing, of the winding up.

(4) If:

(a) a person agrees to dispose of a business relating to the manufacture, distribution or sale of therapeutic goods; and

(b) it is agreed that the disposal of that business is to include a transfer of a licence held by that person;

then:

(c) the person who acquires that business is taken to be the holder of the licence; and

(d) that person must, not later than 3 months after the transfer, notify the Secretary that the person has, by reason of that agreement, become an applicant for the licence.

(4A) If a person who is the holder of a licence:

(a) changes his, her or its name; or

(b) being a corporation, amalgamates with another corporation under a name that is different from the name of the holder of the licence;

the person must give notice in writing to the Secretary of the new name of the person, and the circumstance giving rise to it, within 3 months after the occurrence of the circumstance.

(4B) The licence has effect as if it had been granted to the holder in the holder's new name.

(5) When a person notifies the Secretary of an event referred to in paragraph (1)(b), (2)(b), (3)(b), (4)(d) or (4A)(a) or (b), the person must send to the Secretary

sufficient documentary evidence to establish the matter asserted in the notification.

(6) When a person is taken to be the holder of a licence in accordance with this regulation, the Secretary may regard the person as an applicant for the licence and may deal with the notification referred to in paragraph (1)(b), (2)(b), (3)(b), (4)(d) or (4A)(a) or (b) as if it were an application for a licence.

(7) In spite of subregulation (6), a person who is regarded as an applicant for a licence because of the operation of that subsection may continue to manufacture therapeutic goods under the original licence until the application is determined.

(8) If, at any time, the Secretary becomes aware that he or she has not been informed in accordance with this regulation of an event referred to in paragraph (1)(b), (2)(b), (3)(b), (4)(d) or (4A)(a) or (b), the Secretary may cancel the licence to which the event relates.

Part 5—Examination, testing and analysis of goods

23 Interpretation

(1) In this Part, unless the contrary intention appears:

analyst means a person appointed by the Secretary as an analyst (except an official analyst) under regulation 25.

appropriately fastened and sealed: see subregulation (2).

official analyst means a person appointed by the Secretary as an official analyst under regulation 25.

responsible analyst, in relation to the analysis of a sample of therapeutic goods, means an analyst or official analyst who is nominated as a responsible analyst for the sample under paragraph 25(3)(c).

samples officer means an officer of the Department performing duties under the direction of an official analyst.

(2) For the purposes of this Part, a sample of therapeutic goods is ***appropriately fastened and sealed*** if the sample is fastened and sealed:

(a) in a container or package that is marked with a unique identification number or with the name and address of:

(i) the person from whom the sample was taken; or

(ii) for a sample delivered under paragraph 28(5)(h) or subsection 41FN(2) of the Act—the sponsor of the goods; and

(b) so as to prevent the opening of the container or package, and the removal of the unique identification number or the name and address, without breaking the seal.

24 Authorised officer—powers and duties

(1) An authorised officer may, during normal business hours:

(a) for the purpose of exercising the powers and performing the duties of an authorised officer under this regulation, enter the premises of a licence holder, manufacturer in respect of whom a conformity assessment certificate has been issued, or wholesaler on which therapeutic goods are kept for supply; and

(b) inspect the place at which those goods are kept; and

(c) take samples of those goods; and

(d) ask the owner of therapeutic goods, or the person apparently in charge of those goods, for information relevant to the manufacture and testing of those goods.

(2) If the entry of goods in the Register is subject to the condition that the sponsor of the goods comply with this regulation, the powers of an authorised officer

referred to in subregulation (1) extend to the sponsor as if the sponsor were a licence holder or a manufacturer in respect of whom a conformity assessment certificate has been issued.

25 Appointment of analysts and official analysts and powers of official analysts

(1) The Secretary may, in writing, appoint a person who has appropriate qualifications and experience to be an analyst or an official analyst for the purposes of these Regulations.

(3) In addition to the other powers and functions of an official analyst, an official analyst may:

(a) ask an authorised officer to take samples of therapeutic goods; and

(b) determine the tests that are to be performed on a sample taken under paragraph (a) or delivered under paragraph 28(5)(h) or subsection 41FN(2) of the Act; and

(c) nominate an analyst or official analyst to be the responsible analyst for a sample taken under paragraph (a) or delivered under paragraph 28(5)(h) or subsection 41FN(2) of the Act.

(4) The tests determined under paragraph (3)(b), by an official analyst, for the following matters must be tests covered by regulation 28:

(a) determining whether particular therapeutic goods (other than medical devices) are goods that conform with a standard applicable to the goods;

(b) determining whether a particular kind of medical device complies with the applicable provisions of the essential principles.

(5) The tests determined under paragraph (3)(b), by an official analyst, for a matter not covered by subregulation (4), are the tests that the official analyst considers appropriate.

26 Taking of samples for testing

(1) When an authorised officer takes a sample of therapeutic goods (other than a further sample taken under the circumstances described in subregulation 30(6)), the authorised officer:

(a) must notify the person from whom the sample was taken that the authorised officer is going to send the sample to a laboratory operated by the Department for analysis; and

(b) must give the person from whom the sample was taken a notice setting out details of the goods taken and, if the person from whom the sample was taken was not the sponsor of the goods, send a copy of that notice to the sponsor of the goods; and

(c) must forward the whole or part of the sample to the relevant laboratory.

(2) An authorised officer must ensure that any sample of goods taken (including further samples taken under the circumstances described in subregulation 30(6)) is:

(a) appropriately fastened and sealed; and

(b) stored and transported in accordance with the instructions (if any) specified on the label of the goods.

26A Receiving samples for testing

(1) When a sample of therapeutic goods is delivered under paragraph 28(5)(h) or subsection 41FN(2) of the Act, the Secretary must as soon as practicable:
  (a) determine whether the sample is appropriately fastened and sealed; and
  (b) do either of the following:
    (i) if the sample is appropriately fastened and sealed—send the sample, in the form in which it was received, to the relevant laboratory operated by the Department for analysis;
    (ii) if the sample is not appropriately fastened and sealed—return the sample to the sponsor of the goods, with a statement explaining in what way the sample is not appropriately fastened or sealed.

(2) In complying with subregulation (1), the Secretary must ensure that the sample is stored and transported in accordance with the instructions (if any) specified on the label of the goods.

27 Examination and testing of sample

(1) A samples officer must, as soon as practicable after receiving a sample of goods at a laboratory operated by the Department:
  (a) determine whether the sample is appropriately fastened and sealed; and
  (b) if the sample is appropriately fastened and sealed—store the sample under the officer's control and under secure conditions that are appropriate to the kind of goods.

(2) The responsible analyst must, as soon as practicable, collect the sample from the samples officer and arrange for:
  (a) an analysis of the sample by performing the tests determined under paragraph 25(3)(b) in relation to the sample to establish:
    (i) the quantity and quality of the goods comprising the sample; and
    (ii) any other matter relevant to determining whether:
      (A) for goods other than medical devices—the goods from which the sample was taken conform with any standard applicable to the goods and any conditions relating to matters mentioned in paragraph 28(2)(d) of the Act; and
      (B) for medical devices—the goods from which the sample was taken comply with the applicable provisions of the essential principles and any conditions relating to matters mentioned in paragraph 41FO(2)(d) of the Act; and
    (iii) for a sample of medicine listed under section 26A or 26AE of the Act—whether the medicine contains an ingredient that is not specified in a determination under paragraph 26BB(1)(a) of the Act or whether any of the requirements determined under paragraph 26BB(1)(b) of the Act have been contravened; and

(b) an examination of the goods, the label (if any) relating to the goods and the packaging of the goods, to determine whether the goods comply with the labelling, packaging and other requirements (including requirements relating to advertising) applicable to the goods.

28 Tests for determining conformity with a standard or compliance with essential principles

(1) Each of the following is a test for determining whether particular therapeutic goods (other than medical devices) are goods that conform with a standard applicable to the goods:

(a) a test specified by the Minister in an order under section 10 of the Act for those goods in relation to that standard; and

(b) a test specified in a monograph in the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopeia-National Formulary in relation to that standard if:

(i) those goods are for use in humans; and

(ii) the Minister has not specified a test in an order under section 10 of the Act for those goods in relation to that standard; and

(d) a test accepted for the purposes of registration of the goods under Part 3-2 of the Act; and

(e) any other suitable test that the Secretary requires to be carried out in respect of those goods in relation to that standard.

(2) Each of the following is a test for determining whether a particular kind of medical device complies with the applicable provisions of the essential principles:

(a) a test specified in a medical device standard or conformity assessment standard for the kind of device;

(b) a test accepted for the purpose of issuing a conformity assessment certificate in respect of the kind of device;

(c) a test required under paragraph 41FO(2)(d) of the Act as a condition of inclusion of the kind of device in the Register;

(d) any other suitable test that the Secretary requires to be carried out in respect of the kind of device for the purpose of demonstrating compliance with the applicable provisions of the essential principles.

29 Certificate of responsible analyst

(1) The responsible analyst must issue a certificate setting out the results of the examination and analysis.

(2) Within a reasonable time of the completion of the analysis, the responsible analyst must send a copy of the certificate to:

(a) the sponsor of the goods; and

(b) if the sample was taken under paragraph 25(3)(a) and the person from whom the sample was taken is not the sponsor of the goods—the person from whom the sample was taken.

(4) If the certificate referred to in subregulation (1) states:

(a) for relevant goods other than medical devices—that the goods do not conform with a specified standard or comply with a requirement that is applicable to the goods under regulation 27; or

(b) for medical devices—that the goods do not comply with the applicable provisions of the essential principles or a requirement that is applicable to the goods under regulation 27;

a copy of the certificate sent under subregulation (2) must be accompanied by a notice that complies with subregulation (4A).

(4A) For subregulation (4), the notice must:

(a) state that the person to whom the copy is sent may ask for the results of the analysis referred to in the copy to be reviewed in accordance with regulation 30; and

(b) specify the time within which a request for a review of the results may be made; and

(c) state that the person may ask for an extension of that time if it is not reasonable to expect the person to comply with regulation 30 within the specified time.

(5) In proceedings under the Act or these Regulations, a certificate issued under subregulation (1), or a copy of that certificate, is, in the absence of evidence to the contrary, conclusive proof of the matters set out or stated in it.

(6) A document purporting to be:

(a) a certificate issued under subregulation (1); or

(b) a copy of that certificate;

is, in the absence of evidence to the contrary, to be taken to be the certificate or a copy of the certificate.

30 Review of results of examination and analysis

(1) A person:

(a) to whom a copy of a certificate, setting out the results of the examination and analysis of goods, is sent under subregulation 29(2); and

(b) who sends to the Secretary evidence in writing establishing that the goods do conform with the specified standard or comply with an applicable requirement, or, for medical devices, do comply with the applicable provisions of the essential principles or an applicable requirement;

may ask for the results of the analysis to be reviewed.

(2) A request for review of the results of the analysis is to be made not later than 21 days after the person receives the copy of the certificate.

(3) The Secretary must extend the period of 21 days if it is not reasonable to expect the person to provide the evidence within the period referred to in subregulation (2).

(4) A person is not to be regarded as having sent the Secretary evidence establishing that goods conform with a specified standard or comply with an applicable requirement, or, for medical devices, comply with the applicable provisions of the essential principles or an applicable requirement, unless that person has sent to the Secretary a certificate of a person (the ***third party***) who has appropriate qualifications and experience setting out:

(a) a statement that the third party has analysed a part of the same sample, or a similar sample from the same batch (if any), of those goods; and

(b) the results of that analysis; and

(c) details of the tests used in the analysis.

(5) If the certificate referred to in subregulation (4) shows that an analysis of goods for the purpose of establishing that the goods conform with a specified standard or comply with an applicable requirement, or, for medical devices, comply with the applicable provisions of the essential principles or an applicable requirement, was carried out in accordance with the tests determined by an official analyst under paragraph 25(3)(b) on the basis of which the certificate referred to in paragraph (1)(a) of this regulation was issued, subregulation (6) applies to those goods.

(6) Unless the results of the analysis of a sample of goods to which this subregulation applies, or other information available to the Secretary in relation to those goods, shows lack of homogeneity in the sample, the Secretary must direct:

(a) if part of the sample remains unimpaired—an official analyst to send so much of the sample as remains unimpaired; or

(b) if no part of the sample remains unimpaired—that a further sample be taken by an authorised officer from the same batch as the original sample and that that further sample be sent;

to a person agreed (who may be an analyst or official analyst) upon by the person who requested the review and the official analyst referred to in subregulation (5), or, in the absence of agreement, to a person nominated (who may be an analyst or official analyst) by the Secretary.

(7) If a sample is sent to a person as mentioned in subregulation (6), the person is to:

(a) analyse the sample of the goods in accordance with the tests determined by an official analyst under paragraph 25(3)(b) on the basis of which the certificate referred to in paragraph (1)(a) of this regulation was issued;

(b) send to the Secretary a certificate, signed by the person, setting out the results of the analysis; and

(c) send a copy of that certificate, signed by the person to the person who requested the review.

(8) A certificate under regulation 29 setting out the results of the analysis of a sample of goods ceases to have effect when the Secretary receives the certificate in relation to those goods under subregulation (7).

(9) If the findings of the responsible analyst are upheld, the sponsor must pay any charges payable to the person to whom a sample is sent as mentioned in subregulation (6) in respect of the analysis of the sample.

(10) In proceedings under the Act or these Regulations, a certificate issued under subregulation (7) or a copy of that certificate is, in the absence of evidence to the contrary, conclusive proof of the matters stated in it.

(11) A document purporting to be:

(a) a certificate of a person issued under subregulation (7); or

(b) a copy of that certificate, and purporting to be signed by the person;

is, in the absence of evidence to the contrary, to be regarded as the certificate or a copy of the certificate.

31 Payment for samples

(1) If a sample of therapeutic goods is taken by an authorised officer, the Commonwealth is liable to pay the owner of the goods from which the sample was taken an amount equal to the value of any part of the sample removed by the authorised officer.

(1A) If a sample of therapeutic goods delivered under paragraph 28(5)(h) or subsection 41FN(2) of the Act is sent to a laboratory for analysis, the Commonwealth is liable to pay to the person in relation to whom the goods are entered on the Register an amount equal to the value of the sample.

(2) The amount the Commonwealth is liable to pay is to be worked out on the basis of the market value of the sample when the sample was taken by the authorised officer or delivered under paragraph 28(5)(h) or subsection 41FN(2) of the Act.

32 Offences relating to analysis etc

(1) A person must not:

(a) molest, obstruct or try to intimidate or influence an authorised officer in the execution of his or her powers or the performance of his or her duties under these Regulations; or

(b) on being asked by an authorised officer, fail:

(i) to show the authorised officer the place where any therapeutic goods are kept; or

(ii) to admit the authorised officer to a place where therapeutic goods are kept; or

(iii) to show the authorised officer, or let the authorised officer inspect, therapeutic goods kept by the person; or

(iv) to allow a sample of therapeutic goods to be taken in accordance with these Regulations; or

(v) to give an authorised officer information required by the authorised officer, being information relevant to the manufacture and testing of therapeutic goods that the person is able to provide; or

(vi) to assist the authorised officer in the execution of his or her powers or the performance of his or her duties under these Regulations; or

(c) on being asked by an official analyst, fail to give any information required by the official analyst, being information relevant to the testing of therapeutic goods, that that person is able to provide.

Penalty: 10 penalty units.

(1A) For the purposes of an offence under paragraph (1)(a), strict liability applies to the physical element that the duties mentioned in that paragraph are duties under these Regulations.

Note: For ***strict liability***, see section 6.1 of the *Criminal Code*.

(1B) An offence under paragraph (1)(b) or (c) is an offence of strict liability.

Note: For ***strict liability***, see section 6.1 of the *Criminal Code*.

(1C) It is a defence to a prosecution under paragraph (1)(b) or (c) if the person has a reasonable excuse.

Note: A defendant bears an evidential burden in relation to the matter mentioned in subregulation (1C) (see section 13.3 of the *Criminal Code*).

(2) It is a reasonable excuse for a person to fail to comply with a request for information under paragraph (1)(b) or (c) if compliance with that request would tend to incriminate that person.

33 Identity cards

(1) The Secretary is to ensure that each authorised officer is issued with an identity card that incorporates a recent photograph of the person.

(2) Where the authorised officer enters premises in the course of his or her duties under this Part, the authorised officer must, if requested to do so by any person at those premises, produce his or her identity card for inspection by that person.

(3) When a person ceases to be an authorised officer, the person must, as soon as practicable after so ceasing, return the person's identity card to the Secretary.

Penalty: 1 penalty unit.

(4) An offence under subregulation (3) is an offence of strict liability.

Note: For ***strict liability***, see section 6.1 of the *Criminal Code*.

Part 5A—Exceptional release

33A Prescribed circumstances under which biologicals may be imported, exported or supplied

For paragraphs 14(5A)(b), (9A)(b), (13A)(b), 14A(1A)(b), (2A)(b) and (3A)(b) of the Act, the circumstances are:

(a) the patient has been clinically assessed by the treating medical practitioner to require the biological urgently to treat a serious condition; and

(b) a biological that is included in the Register under Part 3-2A of the Act and conforms with the applicable manufacturing requirements and standards is not available, or is not available within the time necessary for treatment to occur; and

(c) a nonconforming biological that is included in the Register under Part 3-2A of the Act is available; and

(d) no other treatment option is suitable for the patient; and

(e) the nonconforming biological is assessed as the most suitable treatment for the patient; and

(f) the nonconforming biological is to be used only for the treatment of one patient.

33B Conditions for supply of biologicals

(1) For subsection 15AB(1) of the Act, the conditions are that:

(a) all the circumstances mentioned in regulation 33A have occurred; and

(b) the sponsor of the nonconforming biological mentioned in paragraph 33A(c) receives from the treating medical practitioner a copy of a written statement of the following:

(i) the proposal to use the nonconforming biological;

(ii) that the patient or guardian has been told about the likely risks and benefits from the use of the biological;

(iii) why the biological is nonconforming with standards applicable to the biological or was not manufactured in accordance with relevant manufacturing principles under section 36 of the Act; and

(c) the medical or scientific director of the sponsor's facility from which the supply of the biological is to occur must give written approval for release of the biological; and

(d) before the biological is used:

(i) the patient or the patient's guardian must give written informed consent; or

(ii) the treating medical practitioner must give written statement of the reasons that consent cannot be given; and

(e) the consent and the approval must be placed on the patient's medical records and a copy must be given to the treating medical practitioner.

(2) Within 28 days after the release of the nonconforming biological, the sponsor must give to the Secretary:

(a) a notification of use of the nonconforming biological, on a form approved by the Secretary; and

(b) a copy of the documents mentioned in paragraphs (1)(b) to (d); and

(c) any other information requested by the Secretary, including any information requested after submission of the notification.

(3) The Secretary must give the sponsor written acknowledgement of the receipt of the notification within 28 days after receiving the notification and any further information requested by the Secretary.

33C Report on release of nonconforming biological

For each nonconforming biological released from a cell or tissue bank, the sponsor of the nonconforming biological must give to the Secretary:

(a) within 6 months after the release—a report that includes the following information:

(i) date of release;

(ii) product identification details;

(iii) name and address of transplant centre or medical practitioner to whom the nonconforming biological was released;

(iv) initials, gender and date of birth of patient;

(v) any adverse events relating to the use of the nonconforming biological; and

(b) within 14 days after a request by the Secretary—information about the supply of the nonconforming biological and the circumstances surrounding the supply, including:

(i) the decision making process leading to the supply; and

(ii) any adverse events related to the supply.

Part 6—Committees

Division 1A—Advisory Committee on Medicines

35 Establishment

The Advisory Committee on Medicines is established.

35A Functions

(1) The committee's functions are, at the request of the Minister or Secretary, to provide advice and to make recommendations to the Minister or Secretary about one or more of the following matters:
  (a) the safety, quality and efficacy of medicines, including in relation to pharmacovigilance;
  (b) the entry of a medicine in the Register;
  (c) the variation of an entry for a medicine in the Register;
  (d) the continued retention of a medicine in, or the removal of a medicine from, the Register;
  (e) risk assessment and risk management of medicines;
  (f) any other matter (whether or not related to a medicine), including a matter related to standards.

(2) The Minister or Secretary may require the committee to give its advice to other persons or bodies.

35B Membership

(1) The Minister may appoint, in writing, up to 20 persons to the committee in accordance with subregulations (1A) and (1B).

(1A) Subject to subregulation (1B):
  (a) to the extent reasonably practicable, membership of the committee is to represent the widest possible range of fields mentioned in subregulation (2); and
  (b) each member of the committee must have expertise in at least one of those fields.

(1B) One member of the committee may have expertise in consumer health issues.

(2) For the purposes of subregulation (1A), the fields are as follows:
  (a) general medical practice in Australia;
  (b) specialist medical practice of a kind that is relevant to the committee's functions;
  (c) epidemiology or biostatistics;
  (d) clinical pharmacology or pharmacokinetics;

(e) paediatrics;
(f) gerontology;
(g) internal medicine, including the following:
  (i) haematology;
  (ii) oncology;
  (iii) infectious diseases;
  (iv) cardiology;
  (v) gastroenterology or hepatology;
  (vi) renal disease;
  (vii) endocrinology;
  (viii) neurology;
  (ix) immunology;
  (x) rheumatology;
  (xi) respiratory disease;
(h) intensive care;
(i) anaesthetics;
(j) psychiatry;
(k) toxicology;
(l) pharmaceutical chemistry;
(m) microbiology;
(n) community or clinical pharmacy;
(o) manufacture of medicines;
(p) dermatology;
(q) obstetrics or gynaecology;
(r) ophthalmology;
(s) radiology;
(t) medical genetics;
(u) developmental or reproductive toxicology;
(v) medicines in pregnancy;
(w) medical ethics.

Division 1D—Advisory Committee on Medical Devices

38 Establishment

The Advisory Committee on Medical Devices is established.

38A Functions

(1) The committee's functions are, at the request of the Minister or Secretary, to provide advice and to make recommendations to the Minister or Secretary about one or more of the following matters:

(aa) the safety, performance and manufacturing of a medical device;

(a) the inclusion of a medical device or other therapeutic goods in the Register;

(b) the variation of an entry for a medical device or other therapeutic goods in the Register;

(c) the continued retention of a medical device or other therapeutic good in, or the removal of a medical device or other therapeutic good from, the Register;

(d) risk assessment and risk management of medical devices;

(e) any other matter (whether or not related to a medical device or other therapeutic goods).

(2) The Minister or Secretary may require the committee to give its advice to other persons or bodies.

38B Membership

(1) The Minister may appoint, in writing, up to 16 persons to the committee in accordance with subregulations (2) and (3).

(2) Subject to subregulation (3):

(a) to the extent reasonably practicable, membership of the committee is to represent the widest possible range of fields mentioned in subregulations (4) and (5); and

(b) each member of the committee must have either or both of the following:

(i) medical or surgical expertise in one of the fields mentioned in subregulation (4);

(ii) expertise in at least one of the fields mentioned in subregulation (5).

(3) One member of the committee may have expertise in consumer health issues.

(4) For the purposes of paragraph (2)(a) and subparagraph (2)(b)(i), the fields are as follows:

(a) anaesthetics;

(b) cardiology;

(c) cardiothoracic surgery;

(d) dentistry or oro-maxillofacial surgery;

(e) ear, nose and throat;
(f) gastroenterology;
(g) neurology;
(h) obstetrics or gynaecology;
(i) ophthalmology;
(j) orthopaedics;
(k) pathology;
(l) plastic and reconstructive surgery;
(m) renal;
(n) respiratory medicine;
(o) vascular medicine;
(p) any other medical or surgical field of expertise that is relevant to the committee's functions.

(5) For the purposes of paragraph (2)(a) and subparagraph (2)(b)(ii), the fields are as follows:
(a) biomedical engineering or biomaterials;
(b) epidemiology or biostatistics;
(c) general medical practice in Australia;
(d) human factors analysis;
(e) interventional cardiology;
(f) interventional radiology;
(g) manufacture of medical devices;
(h) medical device software engineering;
(i) nursing;
(j) any other clinical or technical field of expertise that is relevant to the committee's functions.

Division 1E—Advisory Committee on Complementary Medicines

39 Establishment

The Advisory Committee on Complementary Medicines is established.

39A Functions

(1) The committee's functions are, at the request of the Minister or Secretary, to provide advice and to make recommendations to the Minister or Secretary about one or more of the following matters:

(a) the safety, efficacy and manufacturing quality of a complementary medicine;

(b) the safety and quality of ingredients that are, or are proposed to be, included in a determination under subsection 26BB(1) of the Act for a listed complementary medicine;

(c) any requirements that are, or are proposed to be, included in a determination under subsection 26BB(1) of the Act in relation to ingredients for a listed complementary medicine;

(d) the registration or listing of a complementary medicine;

(e) the variation of an entry for a complementary medicine in the Register;

(f) the continued retention of a complementary medicine in, or the removal of a complementary medicine from, the Register;

(g) any other matter (whether or not related to a complementary medicine), including a matter related to standards.

(2) The Minister or Secretary may require the committee to give its advice to other persons or bodies.

39B Membership

(1) The minister may appoint, in writing, up to 8 persons to the committee in accordance with subregulations (1A) and (1B).

(1A) Subject to subregulation (1B):

(a) to the extent reasonably practicable, membership of the committee is to represent the widest possible range of fields mentioned in subregulation (2); and

(b) each member of the committee must have expertise in at least one of those fields.

(1B) One member of the committee may have expertise in consumer health issues.

(2) For the purposes of subregulation (1A), the fields are as follows:

(a) complementary medical practice;

(b) manufacture of medicines;

(d) general medical practice in Australia;

(e) herbal medicine;
(f) naturopathy;
(g) nutrition and nutritional medicine;
(h) pharmacology;
(i) pharmacognosy;
(j) toxicology;
(k) epidemiology.

Division 1EA—Advisory Committee on Biologicals

39C Establishment

The Advisory Committee on Biologicals is established.

39D Functions

(1) The committee's functions are, at the request of the Minister or Secretary, to provide advice and to make recommendations to the Minister or Secretary about one or more of the following matters:

(aa) the safety and efficacy of a biological;

(a) the inclusion of a biological in the Register under Part 3-2A of the Act;

(b) the variation of an entry for a biological included in the Register under Part 3-2A of the Act;

(c) the continued retention of a biological in, or the removal of a biological from, the Register;

(d) any other matter (whether or not related to a biological), including a matter related to standards.

(2) The Minister or Secretary may require the committee to give its advice to other persons or bodies.

39E Membership

(1) The Minister may, in writing, appoint up to 12 persons to the committee in accordance with subregulations (1A) and (1B).

(1A) Subject to subregulation (1B):

(a) to the extent reasonably practicable, membership of the committee is to represent the widest possible range of fields mentioned in subregulation (2); and

(b) each member of the committee must have expertise in at least one of those fields.

(1B) One member of the committee may have expertise in consumer health issues.

(2) For the purposes of subregulation (1A), the fields are as follows:

(a) infectious diseases;

(b) tissue products;

(c) blood products;

(d) cellular therapies, including tissue engineering;

(g) clinical expertise;

(h) epidemiology or biostatistics;

(i) toxicology.

Division 1EB—Advisory Committee on Vaccines

39F Establishment

The Advisory Committee on Vaccines is established.

39G Functions

(1) The committee's functions are, at the request of the Minister or Secretary, to provide advice and to make recommendations to the Minister or Secretary about one or more of the following matters:
  (a) the safety, quality and efficacy of vaccines, including in relation to pharmacovigilance;
  (b) the registration of a vaccine;
  (c) the variation of an entry for a vaccine in the Register;
  (d) the continued retention of a vaccine in, or the removal of a vaccine from, the Register;
  (e) risk assessment and risk management of vaccines;
  (f) any other matter (whether or not related to a vaccine), including a matter related to standards.

(2) The Minister or Secretary may require the committee to give its advice to other persons or bodies.

39H Membership

(1) The Minister may, in writing, appoint up to 10 persons to the committee in accordance with subregulations (1A), (1B) and (2).

(1A) Subject to subregulations (1B) and (2):
  (a) to the extent reasonably practicable, membership of the committee is to represent the widest possible range of fields mentioned in subregulation (3); and
  (b) each member of the committee must have expertise in at least one of those fields.

(1B) One member of the committee may have expertise in consumer health issues.

(2) The Minister may appoint one member from each of the following:
  (a) the Australian Technical Advisory Group on Immunisation;
  (b) the National Immunisation Committee;
  (d) the National Centre for Immunisation Research and Surveillance.

(3) For the purposes of subregulation (1A), the fields are as follows:
  (a) immunology;
  (b) virology;
  (c) bacteriology;

(d) infectious diseases in adults or children;
(e) public health;
(f) epidemiology or biostatistics;
(g) vaccine program implementation;
(h) the provision of immunisation treatment by an individual;
(i) paediatrics;
(j) nursing.

Division 1F—General

40 Application of this Division

This Division applies to committees mentioned in Divisions 1A, 1D, 1E, 1EA and 1EB.

41 Appointment of members

(1) A member is appointed to a committee for the term stated in the member's instrument of appointment.

(2) A term of appointment must not be longer than 3 years.

(3) A member, other than a member mentioned in subregulation (4), must not be appointed for more than 3 consecutive terms.

(4) A member appointed to a committee before the commencement of this subregulation must not be appointed for more than 3 further consecutive terms.

41A Appointment of the chair

The Minister must appoint, in writing, a member of a committee to be its chair.

41B Resignation or vacancy

(1) A member or chair may resign by giving written notice to the Minister.

(2) If a chair ceases to be a member of a committee, the position is taken to be vacant.

41C Termination of appointment

(1) The Minister may terminate a member's appointment on any of the following grounds:
  (a) physical or mental incapacity;
  (b) misbehaviour;
  (c) incompetence;
  (d) bankruptcy;
  (e) failing to comply with the disclosure of interest requirements mentioned in regulation 42.

(2) The Minister must terminate a member's appointment if:
  (a) the member is convicted of an offence punishable by imprisonment for at least 1 year; or
  (b) if the member is absent without leave of absence from 3 consecutive meetings of the committee.

41D Leave of absence

(1) The Minister may grant leave of absence to the chair.

(2) The chair may grant leave of absence to another committee member.

41E Acting members

(1) The Minister may appoint a person to act as a member of a committee.

(2) A person may act as a member of a committee:
  (a) during a vacancy in the office, whether or not an appointment has previously been made to the office; or
  (b) during any period, or during all periods, when the holder of the office is absent from duty or is, for any reason, unable to perform the duties of the office.

(3) A person appointed to act in an office must, to the extent reasonably practicable:
  (a) if a particular qualification is required for a substantive member—hold that qualification; or
  (b) if different qualifications are required for all members of the committee—hold 1 of those qualifications.

(4) A person appointed to act during a vacancy must not continue to act for more than 12 months.

41F Committee procedures

In performing its functions, a committee:
  (a) must act in accordance with this Division; and
  (b) must act with as little formality and as quickly as this Division and a proper consideration of the issues before the committee allow; and
  (c) is not bound by the rules of evidence; and
  (d) may obtain information about an issue in any way it considers appropriate (subject to subregulation 42(9)); and
  (e) may receive information or submissions orally or in writing; and
  (f) must comply with any directions given, in writing, to the committee by the Minister or the Secretary about the committee's performance of its functions (other than a direction about advice given or proposed to be given by the committee).

41G Meetings

(1) The chair of a committee may give written notice to the committee, or to some members of the committee, directing the committee, or those members, to hold meetings at the times and places, and to deal with the matters in the manner, stated in the notice.

(2) The procedure of a meeting must be determined by the committee in accordance with this Division.

41H Presiding member

(1) The chair must preside at a committee meeting or nominate a member of the committee to preside at the meeting.

(2) If the chair is temporarily absent from a meeting, the member chosen by the members present must preside at the meeting.

(3) A member chosen to preside under subregulation (2) may exercise the powers and functions of the chair.

41I Quorum

A quorum exists at a committee meeting when:

(a) at least half of the members are present; or

(b) at least half of the members who have been directed to hold the meeting under subregulation 41G(1) are present.

41J Voting

(1) A decision made at a committee meeting by a majority of the votes of the members present and voting is a decision of the committee.

(2) The member presiding at a committee meeting has a deliberative vote and, if the votes are equal, also has a casting vote.

42 Miscellaneous

Sitting fees and travel entitlements

(1) A member of a committee is entitled to sitting fees and travel entitlements as determined by the Remuneration Tribunal.

When committee may establish subcommittees

(2) A committee, with the approval of the Secretary, may establish subcommittees, consisting of members and other persons.

(3) The function of the subcommittee is to inquire into, and report to the committee on, any matter referred to the subcommittee that is within the functions of the committee.

Disclosure of interests

(4) A member of a committee who is aware that he or she has a direct or indirect material personal interest (whether pecuniary or not) in a matter being considered or about to be considered at a meeting of the committee must, without delay, disclose the nature of the interest at, or before, the meeting of the committee.

(5) The disclosure must be recorded in the minutes of the meeting and the member must not, unless the committee otherwise determines, either be present during any deliberation of the committee about the matter or take part in any decision of the committee about that matter.

(6) When a committee is making a determination about a member who has made a disclosure, the member, and any other member who has a direct or indirect material personal interest (whether pecuniary or not) in the matter to which the disclosure relates, must not either be present during any deliberation of the committee or take part in making the determination.

(7) A member of a subcommittee appointed by a committee, who is aware that he or she has a direct or indirect material personal interest (whether pecuniary or not) in a matter being considered, or about to be considered, at a meeting of the subcommittee must, without delay, disclose the nature of the interest at, or before, the meeting of the subcommittee.

Seeking further advice

(8) Any advice or recommendation given by a committee to the Minister or the Secretary may be given to another expert advisory committee for the advice of that committee.

(9) In performing its functions, a committee may seek advice from other persons.

Validity of acts of members

(10) Anything done by a person purporting to be or act as a member (including a chair) is not invalid because:
  (a) the person had not yet been appointed; or
  (b) there is a defect or irregularity in connection with the person's appointment; or
  (c) the person's appointment had ceased to have effect.

Records and reports

(11) A committee must keep a record of its proceedings, and must prepare any other report about its activities that is requested by the Minister or the Secretary.

Publication of recommendations of committees

(12) The Secretary must publish the recommendations of each committee.

Division 3A—Advisory Committee on Medicines Scheduling

Subdivision 3A.1—Preliminary

42ZCA Definitions for Division 3A

In this Division:

appointed member means a member of the Committee appointed by the Minister under subregulation 42ZCD(1).

Committee means the Advisory Committee on Medicines Scheduling.

Note: The Committee is established by section 52B of the Act.

Committee member means an appointed member or a nominated member.

nominated member means a member of the Committee nominated under subsection 52B(3) of the Act in accordance with regulation 42ZCE.

Subdivision 3A.2—Constitution of Committee

42ZCB Membership of Committee

For subsection 52B(2) of the Act, the Committee is to be constituted in accordance with this Subdivision.

42ZCC Committee members

(1) The Committee comprises each nominated member and no more than 8 appointed members.

(2) A Committee member must have expertise in at least one of the following fields:
- (a) the regulation of scheduled medicines in Australia;
- (b) toxicology or pharmacology;
- (c) clinical pharmacology;
- (d) pharmacy practice;
- (e) medical practice;
- (f) consumer health issues relating to the regulation of therapeutic goods;
- (g) industry issues relating to the regulation of therapeutic goods.

(3) Membership of the Committee must, to the extent reasonably practicable, represent the widest possible range of the fields mentioned in subregulation (2).

42ZCD Appointed members

(1) An appointed member must be appointed in writing by the Minister.

(2) The term of an appointment of an appointed member is as specified in the instrument of appointment but must not be longer than 3 years.

(3) An appointed member must not be appointed for more than 3 consecutive terms.

42ZCE Nominated members

(1) This regulation is made for subsection 52B(3) of the Act.

(2) A nomination must be in writing.

(3) The nomination must specify the term of the nominee's membership of the Committee.

(4) The nominee becomes a member of the Committee when the nomination is given to the Minister.

(5) A nominated member stops being a member if:
  (a) the body that nominated the member gives the Minister written notice that the member's nomination is withdrawn; or
  (b) the member, by written notice given to the Minister under subregulation 42ZCG(1), resigns from the Committee.

(6) The Commonwealth, each State, the Australian Capital Territory and the Northern Territory may, by written notice given to the Minister, nominate a member (the ***temporary nominee***) to temporarily replace an existing member nominated by the Commonwealth, the State or Territory:
  (a) during a vacancy in the existing member's office; or
  (b) during any period, or all periods, when the existing member is:
    (i) absent from duty or from Australia; or
    (ii) for any other reason unable to perform the functions of a nominated member.

(7) The temporary nominee becomes a member of the Committee, and the existing member stops being a member of the Committee:
  (a) when the circumstance giving rise to the temporary replacement commences; and
  (b) until that circumstance ends.

42ZCF Appointment of the Chair and acting Chair

(1) The Minister must, in writing, appoint a Committee member to be the Chair of the Committee.

(2) The Chair is appointed for the term stated in the appointment but may be reappointed for further terms.

(3) The Minister may, in writing, appoint a Committee member to act as the Chair:
  (a) during a vacancy in the office of the Chair, whether or not an appointment has previously been made to the office; or
  (b) during any period, or during all periods, when the Chair is absent from duty or from Australia, or is, for any other reason, unable to perform the functions of the Chair.

Note: Section 33A of the *Acts interpretation Act 1901* sets out various matters about acting appointments, including how long a person can act in a vacant office.

42ZCG Resignation or vacancy

(1) A Committee member or Chair may resign by giving written notice to the Minister.

(2) If the Chair ceases to be a Committee member, the position is taken to be vacant.

42ZCH Termination of appointment

(1) The Minister may terminate an appointed member's appointment on any of the following grounds:
  (a) physical or mental incapacity;
  (b) misbehaviour;
  (c) incompetence;
  (d) bankruptcy;
  (e) failing to comply with the disclosure of interest requirements mentioned in regulation 42ZCP.

(2) The Minister must terminate an appointed member's appointment if:
  (a) the member is convicted of an offence punishable by imprisonment for at least 1 year; or
  (b) if the member is absent without leave of absence from 3 consecutive meetings of the Committee.

42ZCI Leave of absence

(1) The Minister may grant leave of absence to the Chair.

(2) The Chair may grant leave of absence to a Committee member.

42ZCJ Acting members

(1) The Minister may, in writing, appoint a person to act as an appointed member:
  (a) during a vacancy in the office of an appointed member, whether or not an appointment has previously been made to the office; or
  (b) during any period, or during all periods, when an appointed member is absent from duty or from Australia, or is, for any reason, unable to perform the duties of the office.

(2) A person appointed to act as an appointed member must have the expertise required for a substantive member.

Note: Section 33A of the *Acts interpretation Act 1901* sets out various matters about acting appointments, including how long a person can act in a vacant office.

Subdivision 3A.3—Committee meetings

42ZCK Committee meetings

For subsection 52B(2) of the Act, the Committee is to hold meetings in accordance with this Subdivision.

42ZCL Meeting procedure

(1) The Chair of the Committee may give written notice to the Committee directing the Committee to hold meetings at the times and places, and to deal with the matters in the manner, stated in the notice.

(2) The procedure of a meeting must be determined by the Committee in accordance with this Subdivision.

(3) If the Chair of the Committee considers it appropriate and efficient in the circumstances, the Chair may direct the Committee to meet by video conference or teleconference or to meet out of session.

(4) At a meeting, the Committee:
  (a) must act with as little formality and as quickly as this Subdivision and a proper consideration of the issues before the Committee allow; and
  (b) is not bound by the rules of evidence; and
  (c) may obtain information about an issue in any way it considers appropriate; and
  (d) may receive information in any way it considers appropriate; and
  (e) must comply with any directions given, in writing, to the Committee by the Minister or the Secretary about the Committee's performance of its functions (other than a direction about advice given or proposed to be given by the Committee).

(5) For this regulation:

out of session, in relation to a meeting, means a meeting in which the members take part by correspondence, email, telephone or in any other way that does not involve formal simultaneous meeting and voting.

42ZCM Presiding member

(1) The Chair must preside at a Committee meeting at which he or she is present.

(2) If the Chair is unable to preside at a meeting, he or she must:
  (a) select a member of the Committee to preside at the meeting; and
  (b) advise the other Committee members of the selection.

(3) If the Chair is temporarily absent from a meeting, the member chosen by the Committee members present must preside at the meeting.

(4) A member presiding under subregulation (2) or (3) may exercise the powers and functions of the Chair.

42ZCN Quorum

A quorum exists at a Committee meeting when at least half of the Committee members are present.

42ZCO Voting

(1) A decision made at a Committee meeting by a majority of the votes of the members present and voting is a decision of the Committee.

Note: Decisions of the Committee relate to the recommendations and advice the Committee provides to the Secretary under subsection 52B(4) of the Act.

(2) The member presiding at a Committee meeting has a deliberative vote and, if the votes are equal, also has a casting vote.

42ZCP Miscellaneous

Sitting fees and travel entitlements

(1) An appointed member is entitled to sitting fees and travel entitlements as determined by the Remuneration Tribunal.

When Committee may establish subcommittees

(2) The Committee, with the approval of the Secretary, may establish subcommittees, consisting of Committee members and other persons.

(3) The function of a subcommittee is to inquire into, and report to the Committee on, any matter referred to the subcommittee that is within the functions of the Committee.

Disclosure of interests

(4) A Committee member who is aware that he or she has a direct or indirect material personal interest (whether pecuniary or not) in a matter being considered or about to be considered at a meeting of the Committee must, without delay, disclose the nature of the interest at, or before, the meeting of the Committee.

(5) The disclosure must be recorded in the minutes of the meeting and the member must not, unless the Committee otherwise determines, either be present during any deliberation of the Committee about the matter or take part in any decision of the Committee about the matter.

(6) When the Committee is making a determination about a member who has made a disclosure, the member, and any other member who has a direct or indirect material personal interest (whether pecuniary or not) in the matter to which the disclosure relates, must not be present during any deliberation of the Committee and must not take part in making the determination.

(7) A member of a subcommittee appointed by the Committee, who is aware that he or she has a direct or indirect material personal interest (whether pecuniary or not) in a matter being considered, or about to be considered, at a meeting of the subcommittee must, without delay, disclose the nature of the interest at, or before, the meeting of the subcommittee.

Seeking and providing further advice

(8) Any advice or recommendation given by the Committee to the Secretary may be given to another committee established under the Act or these Regulations for the advice of that committee.

(9) In performing its functions, the Committee may seek advice from other persons.

Validity of acts of members

(10) Anything done by a person purporting to be, or purporting to act as, a Committee member (including the Chair) is not invalid because:
  (a) the person had not yet been appointed; or
  (b) there is a defect or irregularity in connection with the person's appointment; or
  (c) the person's appointment had ceased to have effect.

Records and reports

(11) The Committee must keep a record of its proceedings, and must prepare any other report about its activities that is requested by the Minister or the Secretary.

Publication

(12) The Committee must publish details of any recommendations it makes.

Division 3B—Advisory Committee on Chemicals Scheduling

Subdivision 3B.1—Preliminary

42ZCQ Definitions for Division 3B

In this Division:

appointed member means a member of the Committee appointed by the Minister under subregulation 42ZCT(1).

Committee means the Advisory Committee on Chemicals Scheduling.

Note: The Committee is established by section 52C of the Act.

Committee member means an appointed member or a nominated member.

nominated member means a member of the Committee nominated under subsection 52C(3) of the Act in accordance with regulation 42ZCU.

Subdivision 3B.2—Constitution of Committee

42ZCR Membership of Committee

For subsection 52C(2) of the Act, the Committee is to be constituted in accordance with this Subdivision.

42ZCS Committee members

(1) The Committee comprises each nominated member and no more than 8 appointed members.

(2) A Committee member must have expertise in at least one of the following fields:
- (a) the regulation of scheduled chemicals in Australia;
- (b) veterinary medicine or veterinary pathology;
- (c) toxicology;
- (d) industrial or domestic chemicals;
- (e) agricultural or veterinary chemicals;
- (f) clinical aspects of human poisoning;
- (g) occupational health, particularly as a medical practitioner;
- (h) consumer health issues relating to the regulation of chemicals;
- (i) industry issues relating to the regulation of chemicals.

(3) Membership of the Committee must, to the extent reasonably practicable, represent the widest possible range of the fields mentioned in subregulation (2).

42ZCT Appointed members

(1) An appointed member must be appointed in writing by the Minister.

(2) The term of an appointment of an appointed member is as specified in the instrument of appointment but must not be longer than 3 years.

(3) An appointed member must not be appointed for more than 3 consecutive terms.

42ZCU Nominated members

(1) This regulation is made for subsection 52C(3) of the Act.

(2) A nomination must be in writing.

(3) The nomination must specify the term of the nominee's membership of the Committee.

(4) The nominee becomes a member of the Committee when the nomination is given to the Minister.

(5) A nominated member stops being a member if:
  (a) the body that nominated the member gives the Minister written notice that the member's nomination is withdrawn; or
  (b) the member, by written notice given to the Minister under subregulation 42ZCW(1), resigns from the Committee.

(6) The Commonwealth, each State, the Australian Capital Territory and the Northern Territory may, by written notice given to the Minister, nominate a member (the ***temporary nominee***) to temporarily replace an existing member nominated by the Commonwealth, the State or Territory:
  (a) during a vacancy in the existing member's office; or
  (b) during any period, or all periods, when the existing member is:
    (i) absent from duty or from Australia; or
    (ii) for any other reason unable to perform the functions of a nominated member.

(7) The temporary nominee becomes a member of the Committee, and the existing member stops being a member of the Committee:
  (a) when the circumstance giving rise to the temporary replacement commences; and
  (b) until that circumstance ends.

42ZCV Appointment of the Chair and acting Chair

(1) The Minister must, in writing, appoint a Committee member to be the Chair of the Committee.

(2) The Chair is appointed for the term stated in the appointment but may be reappointed for further terms.

(3) The Minister may, in writing, appoint a Committee member to act as the Chair:
  (a) during a vacancy in the office of the Chair, whether or not an appointment has previously been made to the office; or

(b) during any period, or during all periods, when the Chair is absent from duty or from Australia, or is, for any other reason, unable to perform the functions of the Chair.

Note: Section 33A of the *Acts interpretation Act 1901* sets out various matters about acting appointments, including how long a person can act in a vacant office.

42ZCW Resignation or vacancy

(1) A Committee member or Chair may resign by giving written notice to the Minister.

(2) If the Chair ceases to be a Committee member, the position is taken to be vacant.

42ZCX Termination of appointment

(1) The Minister may terminate an appointed member's appointment on any of the following grounds:
(a) physical or mental incapacity;
(b) misbehaviour;
(c) incompetence;
(d) bankruptcy;
(e) failing to comply with the disclosure of interest requirements mentioned in regulation 42ZCZF.

(2) The Minister must terminate an appointed member's appointment if:
(a) the member is convicted of an offence punishable by imprisonment for at least 1 year; or
(b) if the member is absent without leave of absence from 3 consecutive meetings of the Committee.

42ZCY Leave of absence

(1) The Minister may grant leave of absence to the Chair.

(2) The Chair may grant leave of absence to a Committee member.

42ZCZ Acting members

(1) The Minister may, in writing, appoint a person to act as an appointed member:
(a) during a vacancy in the office of an appointed member, whether or not an appointment has previously been made to the office; or
(b) during any period, or during all periods, when an appointed member is absent from duty or from Australia, or is, for any reason, unable to perform the duties of the office.

(2) A person appointed to act as an appointed member must have the expertise required for a substantive member.

Note: Section 33A of the *Acts interpretation Act 1901* sets out various matters about acting appointments, including how long a person can act in a vacant office.

Subdivision 3B.3—Committee meetings

42ZCZA Committee meetings

For subsection 52C(2) of the Act, the Committee is to hold meetings in accordance with this Subdivision.

42ZCZB Meeting procedure—general

(1) The Chair of the Committee may give written notice to the Committee directing the Committee to hold meetings at the times and places, and to deal with the matters in the manner, stated in the notice.

(2) The procedure of a meeting must be determined by the Committee in accordance with this Subdivision.

(3) If the Chair of the Committee considers it appropriate and efficient in the circumstances, the Chair may direct the Committee to meet by video conference or teleconference or to meet out of session.

(4) At a meeting, the Committee:
  (a) must act with as little formality and as quickly as this Subdivision and a proper consideration of the issues before the Committee allow; and
  (b) is not bound by the rules of evidence; and
  (c) may obtain information about an issue in any way it considers appropriate; and
  (d) may receive information in any way it considers appropriate; and
  (e) must comply with any directions given, in writing, to the Committee by the Minister or the Secretary about the Committee's performance of its functions (other than a direction about advice given or proposed to be given by the Committee).

(5) For this regulation:

out of session, in relation to a meeting, means a meeting in which the members take part by correspondence, email, telephone or in any other way that does not involve formal simultaneous meeting and voting.

42ZCZC Presiding member

(1) The Chair must preside at a Committee meeting at which he or she is present.

(2) If the Chair is unable to preside at a meeting, he or she must:
  (a) select a member of the Committee to preside at the meeting; and
  (b) advise the other Committee members of the selection.

(3) If the Chair is temporarily absent from a meeting, the member chosen by the Committee members present must preside at the meeting.

(4) A member presiding under subregulation (2) or (3) may exercise the powers and functions of the Chair.

42ZCZD Quorum

A quorum exists at a Committee meeting when at least half of the Committee members are present.

42ZCZE Voting

(1) A decision made at a Committee meeting by a majority of the votes of the members present and voting is a decision of the Committee.

Note: Decisions of the Committee relate to the recommendations and advice the Committee provides to the Secretary under subsection 52C(4) of the Act.

(2) The member presiding at a Committee meeting has a deliberative vote and, if the votes are equal, also has a casting vote.

42ZCZF Miscellaneous

Sitting fees and travel entitlements

(1) An appointed member is entitled to sitting fees and travel entitlements as determined by the Remuneration Tribunal.

When Committee may establish subcommittees

(2) The Committee, with the approval of the Secretary, may establish subcommittees, consisting of Committee members and other persons.

(3) The function of the subcommittee is to inquire into, and report to the Committee on, any matter referred to the subcommittee that is within the functions of the Committee.

Disclosure of interests

(4) A Committee member who is aware that he or she has a direct or indirect material personal interest (whether pecuniary or not) in a matter being considered or about to be considered at a meeting of the Committee must, without delay, disclose the nature of the interest at, or before, the meeting of the Committee.

(5) The disclosure must be recorded in the minutes of the meeting and the member must not, unless the Committee otherwise determines, either be present during any deliberation of the Committee about the matter or take part in any decision of the Committee about the matter.

(6) When the Committee is making a determination about a member who has made a disclosure, the member, and any other member who has a direct or indirect material personal interest (whether pecuniary or not) in the matter to which the disclosure relates, must not be present during any deliberation of the Committee and must not take part in making the determination.

(7) A member of a subcommittee appointed by the Committee, who is aware that he or she has a direct or indirect material personal interest (whether pecuniary or not) in a matter being considered, or about to be considered, at a meeting of the subcommittee must, without delay, disclose the nature of the interest at, or before, the meeting of the subcommittee.

Seeking and providing further advice

(8) Any advice or recommendation given by the Committee to the Secretary may be given to another committee established under the Act or these Regulations for the advice of that committee.

(9) In performing its functions, the Committee may seek advice from other persons.

Validity of acts of members

(10) Anything done by a person purporting to be, or purporting to act as, a Committee member (including the Chair) is not invalid because:
  (a) the person had not yet been appointed; or
  (b) there is a defect or irregularity in connection with the person's appointment; or
  (c) the person's appointment had ceased to have effect.

Records and reports

(11) The Committee must keep a record of its proceedings, and must prepare any other report about its activities that is requested by the Minister or the Secretary.

Publication

(12) The Committee must publish details of any recommendations it makes.

Division 3C—Joint meetings

42ZCZG Joint meetings

For section 52CA of the Act, the Advisory Committee on Medicines Scheduling and the Advisory Committee on Chemicals Scheduling may hold joint meetings in accordance with this Division.

42ZCZH Procedure for joint meetings

(1) The Secretary may, if the Secretary considers it appropriate to do so, give written notice to the Committee members of both Committees directing the Committees to hold a joint meeting at the time and place, and to deal with the matters in the manner, stated in the notice.

(2) At a joint meeting, the Committee members present at the meeting must vote on which Chair (or presiding member) is to be the Chair of the joint meeting.

(3) For the purpose of choosing a Chair, a Committee member may cast one vote in respect of each Committee of which he or she is a member.

(4) There is a quorum at a joint meeting if there is a quorum for each Committee.

(5) At a joint meeting:
  (a) decisions are to be made by a majority of the votes cast by the members present and voting; and
  (b) each member has one vote in respect of each Committee of which he or she is a member.

(6) A decision made at a joint meeting is taken to be a decision of each Committee for the purposes of any advice or recommendation provided to the Secretary by either Committee.

  Note: Decisions at a joint meeting relate to the recommendations and advice a Committee may provide to the Secretary under subsections 52B(4) and 52C(4) of the Act.

(7) Each Committee must keep a record of the proceedings of the joint meeting.

Division 3D—Procedure for amending the current Poisons Standard

Subdivision 3D.1—Preliminary

42ZCZI Definitions for Division 3D

In this Division:

business day means a day that is not a Saturday, Sunday or public holiday in the Australian Capital Territory.

Committee member means a member of:

(a) the Advisory Committee on Medicines Scheduling; or

(b) the Advisory Committee on Chemicals Scheduling.

expert advisory committee means:

(a) the Advisory Committee on Medicines Scheduling; or

(b) the Advisory Committee on Chemicals Scheduling; or

(c) the Advisory Committee on Medicines Scheduling and the Advisory Committee on Chemicals Scheduling in joint session.

first closing date has the meaning given by paragraph 42ZCZK(1)(d).

interim decision means:

(a) in Subdivision 3D.2—a decision of the Secretary under regulation 42ZCZN; and

(b) in Subdivision 3D.3—a decision of the Secretary under paragraph 42ZCZV(a).

proposed amendment means a proposal to amend the current Poisons Standard under subsection 52D(2) of the Act on the Secretary's own initiative or in response to an application under section 52EAA of the Act.

public submission means a submission under this Division by a person who is not a Committee member.

relevant submission has the meaning given by paragraph 42ZCZQ(1)(a).

second closing date has the meaning given by paragraph 42ZCZP(1)(c).

Note: For ***current Poisons Standard*** see s 52A of the Act.

Subdivision 3D.2—Procedure if proposed amendment referred to expert advisory committee

42ZCZJ Application

(1) For subsection 52D(2) of the Act, this Subdivision sets out the procedure that is to be followed in amending the current Poisons Standard:

(a) if:

(i) a person applies to the Secretary under section 52EAA of the Act to amend the current Poisons Standard; and

(ii) the Secretary decides to refer the proposed amendment to an expert advisory committee; or

(b) if the Secretary decides:

(i) to amend the current Poisons Standard on his or her own initiative; and

(ii) to refer the proposed amendment to an expert advisory committee.

Note: This Subdivision does not limit the way the Secretary may exercise a power under subsection 52D(2) of the Act in other circumstances.

42ZCZK Proposed amendment to be referred to expert advisory committee

(1) The Secretary must publish, in a manner the Secretary considers appropriate, a notice:

(a) specifying the expert advisory committee to which the proposed amendment will be referred; and

(b) specifying the date of the meeting of the committee; and

(c) setting out details of the proposed amendment; and

(d) inviting public submissions to be made to the committee by a date mentioned in the notice as the closing date for public submissions (the ***first closing date***).

(2) The first closing date must be at least 20 business days after publication of the notice.

(3) The date of the meeting must be at least 10 business days after the first closing date.

42ZCZL Consideration of public submissions

(1) At a meeting of an expert advisory committee to consider the proposed amendment, the committee must consider all public submissions received by the first closing date that:

(a) address a matter mentioned in section 52E of the Act; and

(b) are relevant to the proposed amendment.

(2) The committee is not required to consider a public submission received after the first closing date.

(3) Subject to subregulation (4), the Secretary must publish, in a manner the Secretary considers appropriate, all public submissions received on or before the first closing date.

(4) The Secretary must not publish any information that the Secretary considers to be confidential information.

42ZCZM Committee to advise Secretary

After consideration of any public submissions received, the expert advisory committee must provide advice or a recommendation to the Secretary in relation to the proposed amendment.

42ZCZN Interim decision of Secretary

After considering the advice or recommendation of the expert advisory committee, the Secretary must, subject to regulation 42ZCZO, make an interim decision in relation to the proposed amendment.

42ZCZO Secretary may make final decision if no interim decision required

(1) The Secretary may make a final decision without making an interim decision if no public submissions are received in response to an invitation under paragraph 42ZCZK(1)(d).

(2) The Secretary must comply with regulation 42ZCZS after making the final decision.

42ZCZP Call for further submissions

(1) As soon as practicable after making the interim decision, the Secretary must publish, in a manner the Secretary considers appropriate, a notice:
  (a) setting out the interim decision and the reasons for making the interim decision; and
  (b) if the interim decision is to amend the current Poisons Standard—specifying the proposed date of effect of the proposed amendment; and
  (c) inviting interested persons to make submissions to the Secretary in relation to the interim decision by a date mentioned in the notice as the closing date for submissions (the ***second closing date***); and
  (d) if the interim decision is in response to an application made under section 52EAA—inviting the person who made the application to make a submission in relation to the interim decision by the second closing date.

(2) The second closing date must be at least 10 business days after publication of the notice.

42ZCZQ Reconsideration of interim decision

(1) If the Secretary receives further submissions on or before the second closing date, the Secretary must, as soon as practicable after the second closing date:
  (a) consider all public submissions (the ***relevant submissions***) made by the second closing date that:
    (i) address a matter mentioned in section 52E of the Act; and
    (ii) are relevant to the Secretary's interim decision; and
  (b) reconsider the interim decision in light of those submissions and any advice received in response to a request under paragraph (2)(a).

(2) In reconsidering the interim decision, the Secretary:
  (a) may request advice from any committee or any person; and
  (b) is not required to engage in further public consultation.

(3) The Secretary need not consider a public submission made after the second closing date.

(4) Subject to subsection (5), the Secretary must publish, in a manner the Secretary considers appropriate, all relevant submissions.

(5) The Secretary must not publish any information that the Secretary considers to be confidential information.

42ZCZR Final decision if there is an interim decision

The Secretary may make a final decision by confirming, varying or setting aside the interim decision only:
  (a) after considering all relevant submissions and any advice received in response to a request under paragraph 42ZCZQ(2)(a); or
  (b) if there are no such submissions or advice.

42ZCZS Publication of final decision

After making a final decision under regulation 42ZCZR or 42ZCZO, the Secretary must:
  (a) publish, in a manner that the Secretary considers appropriate:
    (i) the decision; and
    (ii) the reasons for the decision; and
    (iii) the date of effect of the decision; and
  (b) if the decision is to amend the current Poisons Standard—make the amendment.

Note: The Secretary must comply with section 52E of the Act when amending the current Poisons Standard.

Subdivision 3D.3—Procedure if proposed amendments not referred to expert advisory committee

42ZCZT Application

This Subdivision applies if the Secretary:
  (a) receives an application under section 52EAA of the Act to amend the current Poisons Standard; and
  (b) decides not to refer the proposed amendment to an expert advisory committee.

Note: This Subdivision does not limit the way the Secretary may exercise a power under subsection 52D(2) of the Act in other circumstances.

42ZCZU Final decision without interim decision

(1) If the Secretary decides to amend the current Poisons Standard in the manner set out in the application, the Secretary may make a final decision without making an interim decision.

(2) The Secretary must comply with regulation 42ZCZX after making the final decision.

42ZCZV Interim decision required if Secretary decides not to amend as requested

If the Secretary decides not to amend the current Poisons Standard in the manner set out in the application, the Secretary must:

(a) make an interim decision on the application having regard to the information provided by the applicant; and

(b) give the applicant a written notice:

(i) setting out the interim decision and the reasons for the decision; and

(ii) advising the applicant that he or she may, within the period specified in the notice (not being less than 10 business days after the date of the notice), make a written submission to the Secretary about the interim decision.

42ZCZW Final decision if there is interim decision

If the Secretary makes an interim decision on the application, the Secretary may make a final decision on the application by confirming, varying or setting aside the interim decision only:

(a) after considering any submission provided by the applicant within the time specified in the notice under paragraph 42ZCZV(b); or

(b) if no submission is received from the applicant within that time.

42ZCZX Publication of final decision

After making a final decision under regulation 42ZCZU or 42ZCZW, the Secretary must:

(a) publish, in a manner that the Secretary considers appropriate:

(i) the decision; and

(ii) the reasons for the decision; and

(iii) the date of effect of the decision; and

(b) if the decision is to amend the current Poisons Standard—make the amendment.

Note: The Secretary must comply with section 52E of the Act when amending the current Poisons Standard.

Part 7—Charges for registration, listing and inclusion, licences, exemptions, costs and fees

Division 1—Charges for registration, listing and inclusion of therapeutic goods, exemptions and licences

Subdivision 1—Preliminary

43AAA Meaning of turnover and when turnover is of low value

(1) For this Division (other than Subdivision 3) and subject to regulation 43AABB, a person's turnover of therapeutic goods for a financial year is of low value if the turnover is $0.

(2) For this Division (other than Subdivision 3) and subject to regulation 43AABB:
  (a) a person's ***turnover*** of therapeutic goods for a financial year commencing on or after 1 July 2015 is the gross amount (in dollars) received (excluding GST) from sales (whether direct or indirect) of the goods in Australia by the person for the financial year; and
  (b) a person's ***turnover*** of therapeutic goods (other than a biological) for a financial year commencing before 1 July 2015 is the person's turnover, as defined by regulation 43AAB of these Regulations as in force immediately before 1 July 2015, for the goods.

Subdivision 1A—Time for payment of certain annual charges

43AAB Time for payment of certain annual charges

Entry of goods in Register commencing in financial year

(1) For paragraph 44(1)(a) of the Act, an annual registration charge, annual listing charge or annual charge for inclusion in the Register for a financial year becomes payable:
  (a) if the person who is liable to pay the charge notifies the Secretary, under regulation 43AAF or 43AAGE, that the person's turnover of the therapeutic goods concerned for the financial year will not be of low value—on the last day of the month commencing after the month in which the notification was given; or
  (b) if the person who is liable to pay the charge does not give the Secretary a declaration relating to the person's turnover of the therapeutic goods concerned for the financial year, in accordance with whichever of regulation 43AAC, 43AAD, 43AAGB or 43AAGC is applicable—on 15 September in the next financial year.

Entry of goods in Register commencing before start of financial year

(2) For subparagraph 44(1)(b)(ii) of the Act, an annual registration charge, annual listing charge or annual charge for inclusion in the Register for a financial year becomes payable on 15 September in that year.

Note 1: A person is not liable to pay an annual registration charge, annual listing charge or annual charge for inclusion in the Register for a financial year if:

(a) the person is exempt from liability to pay the charge for that financial year under Subdivision 2; or

(b) the Secretary has waived the charge for that financial year under regulation 43AAH.

Note 2: This regulation is subject to subsection 44(3) of the Act. That subsection provides that the Secretary may, by notice in writing given to a person, specify a later day on which a charge becomes payable by the person for a financial year.

Subdivision 2—Exemption from liability to pay certain annual charges—therapeutic goods other than IVD devices

43AAAA Application

This Subdivision does not apply to IVD devices.

43AABA Purpose of this Subdivision

For section 44A of the Act, this Subdivision makes provision for and in relation to exempting a person in relation to whom therapeutic goods (other than an IVD device) are registered, listed or included in the Register at any time in a financial year from liability to pay an annual registration charge, annual listing charge or annual charge for inclusion in the Register in respect of the goods for the financial year, if the person's turnover of the goods for the financial year is of low value.

43AABB Exemption from liability to pay certain annual charges—2014-15 financial year—goods entered on Register on or after 1 May 2015 and on or before 30 June 2015

(1) This regulation applies in relation to therapeutic goods (other than a biological) that are registered, listed or included in the Register, if the registration, listing or inclusion commenced on or after 1 May 2015 and on or before 30 June 2015.

(2) The person in relation to whom the goods are registered, listed or included in the Register is taken to have been granted, under Subdivision 2 of Division 1 of Part 7 of these Regulations as in force immediately before 1 July 2015, an exemption from liability to pay an annual registration charge, annual listing charge or annual charge for inclusion in the Register in respect of the goods for the financial year commencing on 1 July 2014, on the ground that the turnover of the goods for that financial year was a low value turnover.

(3) For this regulation, the following expressions have the meaning given by regulation 43AAB of these Regulations, as in force immediately before 1 July 2015:
  (a) low value turnover;
  (b) turnover.

43AAC Exemption from liability to pay certain annual charges—2015-16 financial year

Therapeutic goods other than biologicals

(1) A person in relation to whom therapeutic goods (other than a biological) are registered, listed or included in the Register at any time in the financial year commencing on 1 July 2015 (the ***2015-16 financial year***) is exempt from liability to pay an annual registration charge, annual listing charge or annual charge for inclusion in the Register in respect of the goods for the 2015-16 financial year if the requirements in subregulation (2), (3), (4), (5), (5A) or (5B) are met.

Entry of goods in Register commencing in 2015-2016 financial year

(2) The requirements in this subregulation are met if:
  (a) the registration, listing or inclusion in the Register of the goods commenced in the 2015-16 financial year; and
  (b) the person's turnover of the goods for the 2015-16 financial year is of low value; and
  (c) the person gives the Secretary, on or before 22 July 2016, a declaration, in a form or a manner approved by the Secretary, stating that the person's turnover of the goods for the 2015-16 financial year was of low value.

Entry of goods in Register commencing on or after 1 May 2015 and on or before 30 June 2015

(3) The requirements in this subregulation are met if:
  (a) the registration, listing or inclusion in the Register of the goods commenced on or after 1 May 2015 and on or before 30 June 2015; and
  (b) the person is taken, under regulation 43AABB, to have been granted an exemption from liability to pay an annual registration charge, annual listing charge or annual charge for inclusion in the Register in respect of the goods for the financial year commencing on 1 July 2014 (the ***2014-15 financial year***); and
  (c) the person's turnover of the goods for the 2014-15 financial year was of low value; and
  (d) the person gives the Secretary, on or before 22 July 2016, a declaration, in a form or a manner approved by the Secretary, stating that the person's turnover of the goods for the 2014-15 financial year was of low value; and
  (e) the person's turnover of the goods for the 2015-16 financial years was of low value; and

(f) the person gives the Secretary, on or before 22 July 2016, a declaration, in a form or a manner approved by the Secretary, stating that the person's turnover of the goods for the 2015-16 financial year was of low value.

Entry of goods in Register commencing on or after 1 July 2014 and on or before 30 April 2015

(4) The requirements in this subregulation are met if:

(a) the registration, listing or inclusion in the Register of the goods commenced on or after 1 July 2014 and on or before 30 April 2015; and

(b) either:

(i) the person had been granted an exemption, under Subdivision 2 of Division 1 of Part 7 of these Regulations as in force immediately before 1 July 2015, from liability to pay an annual registration charge, annual listing charge or annual charge for inclusion in the Register in respect of the goods for the 2014-15 financial year; or

(ii) before 1 July 2015, the Finance Minister, under paragraph 63(1)(a) of the *Public Governance, Performance and Accountability Act 2013*, authorised the waiver of an annual registration charge, an annual listing charge or an annual charge for inclusion in the Register in respect of the goods for the 2014-15 financial year; and

(c) the person's turnover of the goods for the 2014-15 financial was of low value; and

(d) the person gives the Secretary, on or before 22 July 2016, a declaration, in a form or a manner approved by the Secretary, stating that the person's turnover of the goods for the 2014-15 financial year was of low value; and

(e) the person's turnover of the goods for the 2015-16 financial years was of low value; and

(f) the person gives the Secretary, on or before 22 July 2016, a declaration, in a form or a manner approved by the Secretary, stating that the person's turnover of the goods for the 2015-16 financial year was of low value.

Entry of goods in Register commencing on or before 30 June 2014

(5) The requirements in this subregulation are met if:

(a) the registration, listing or inclusion in the Register of the goods commenced on or before 30 June 2014; and

(b) for each financial year commencing on or after 1 July 2013 and ending on or before 30 June 2015, either:

(i) the person had been granted an exemption, under Subdivision 2 of Division 1 of Part 7 of these Regulations as in force immediately before 1 July 2015, from liability to pay an annual registration charge, annual listing charge or annual charge for inclusion in the Register in respect of the goods for that financial year; or

(ii) before 1 July 2015, the Finance Minister, under paragraph 63(1)(a) of the *Public Governance, Performance and Accountability Act 2013*, authorised the waiver of an annual registration charge, an annual

listing charge or an annual charge for inclusion in the Register in respect of the goods for that financial year; and

(c) the person's turnover of the goods for each financial year referred to in paragraph (b) was of low value; and

(d) the person gives the Secretary, on or before 22 July 2016, a declaration, in a form or a manner approved by the Secretary, stating that the person's turnover of the goods for each financial year referred to in paragraph (b) was of low value; and

(e) the person's turnover of the goods for the 2015-16 financial years was of low value; and

(f) the person gives the Secretary, on or before 22 July 2016, a declaration, in a form or a manner approved by the Secretary, stating that the person's turnover of the goods for the 2015-16 financial year was of low value.

Inclusion in Register of certain joint replacement medical devices on or after 1 July 2014 and on or before 30 June 2015

(5A) The requirements in this subregulation are met if:

(a) the therapeutic goods are a joint replacement medical device; and

(b) the inclusion in the Register of the joint replacement medical device as a Class III medical device commenced on or after 1 July 2014 and on or before 30 June 2015; and

(c) the medical device is covered by subregulation 11.22(3) of the *Therapeutic Goods (Medical Devices) Regulations 2002*; and

(d) the person's turnover of the medical device for the 2014-15 financial year was of low value; and

(e) the person gives the Secretary, on or before 22 July 2016, a declaration, in a form or a manner approved by the Secretary, stating that the person's turnover of the medical device for the 2014-15 financial year was of low value; and

(f) the person's turnover of the medical device for the 2015-16 financial year was of low value; and

(g) the person gives the Secretary, on or before 22 July 2016, a declaration, in a form or a manner approved by the Secretary, stating that the person's turnover of the medical device for the 2015-16 financial year was of low value.

Inclusion in Register of certain joint replacement medical devices on or before 30 June 2014

(5B) The requirements in this subregulation are met if:

(a) the therapeutic goods are a joint replacement medical device; and

(b) the inclusion in the Register of the joint replacement medical device as a Class III medical device commenced on or before 30 June 2014; and

(c) the medical device is covered by subregulation 11.22(3) of the *Therapeutic Goods (Medical Devices) Regulations 2002*; and

(d) the person's turnover of the medical device for each financial year commencing on or after 1 July 2013 and ending on or before 30 June 2015 year was of low value; and

(e) the person gives the Secretary, on or before 22 July 2016, a declaration, in a form or a manner approved by the Secretary, stating that the person's turnover of the medical device for each financial year referred to in paragraph (d) was of low value; and

(f) the person's turnover of the medical device for the 2015-16 financial year was of low value; and

(g) the person gives the Secretary, on or before 22 July 2016, a declaration, in a form or a manner approved by the Secretary, stating that the person's turnover of the medical device for the 2015-16 financial year was of low value.

Biologicals

(6) A person in relation to whom a biological is included in the Register at any time in the 2015-16 financial year is exempt from liability to pay an annual charge for inclusion of the biological in the Register for the 2015-16 financial year if:

(a) the inclusion of the biological in the Register commenced in the 2015-16 financial year; and

(b) the person's turnover of the goods for the 2015-16 financial year is of low value; and

(c) the person gives the Secretary, on or before 22 July 2016, a declaration, in a form or a manner approved by the Secretary, stating that the person's turnover of the goods for the 2015-16 financial year was of low value.

Note 1: See regulation 43AAA for the meaning of ***turnover*** and when turnover is of low value.

Note 2: A person may commit an offence if the person provides false or misleading information or documents (see sections 137.1 and 137.2 of the *Criminal Code*).

Note 3: If a person is not exempt from liability to pay an annual charge for the 2015-16 financial year only because the person did not give the Secretary the declaration, or declarations, relating to turnover in accordance with this regulation, the person may be exempt from liability to pay the charge for the 2015-16 financial year under regulation 43AAE.

Note 4: If a person becomes aware during the 2015-16 financial year that the person's turnover of the goods for that year will not be of low value, the person may notify the Secretary of that fact under regulation 43AAF.

Note 5: If the Secretary becomes aware that a person's turnover of the goods, for a financial year for which a declaration was given under this regulation, was not of low value, the Secretary may, under regulation 43AAG, notify the person that the person is liable to pay the charge for the 2015-16 financial year.

43AAD Exemption from liability to pay certain annual charges—financial years commencing on or after 1 July 2016

A person in relation to whom therapeutic goods are registered, listed or included in the Register at any time in a financial year commencing on or after 1 July 2016 (the ***current financial year***) is exempt from liability to pay an annual registration charge, annual listing charge or annual charge for inclusion in the Register in respect of the goods for the current financial year if the following requirements are met:

(a) either:
  (i) the person was exempt from liability to pay the charge in respect of the goods for the immediately preceding financial year; or
  (ii) the registration, listing or inclusion in the Register of the goods commenced in the current financial year;

(b) the person's turnover of the goods for the current financial year is of low value;

(c) the person gives the Secretary, on or before 22 July of the next financial year, a declaration, in a form or a manner approved by the Secretary, stating that the person's turnover of the goods for the current financial year was of low value.

Note 1: See regulation 43AAA for the meaning of ***turnover*** and when turnover is of low value.

Note 2: A person may commit an offence if the person provides false or misleading information or documents (see sections 137.1 and 137.2 of the *Criminal Code*).

Note 3: If a person is not exempt from liability to pay an annual charge for the current financial year only because the person did not give the Secretary the declaration relating to turnover in accordance with this regulation, the person may be exempt from liability to pay the charge for the current financial year under regulation 43AAE.

Note 4: If a person becomes aware during the current financial year that the person's turnover of the goods for that year will not be of low value, the person may notify the Secretary of that fact under regulation 43AAF.

Note 5: If the Secretary becomes aware that a person's turnover of the goods for the current financial year was not of low value, the Secretary may, under regulation 43AAG, notify the person that the person is liable to pay the charge for the current financial year.

43AAE Exemption from liability to pay certain annual charges—late notice that turnover was of low value

(1) This regulation applies if a person would have been exempt from liability to pay an annual registration charge, annual listing charge or annual charge for inclusion in the Register in respect of therapeutic goods for a financial year commencing on or after 1 July 2015 (the ***relevant financial year***), except that the person did not give the Secretary a declaration, or declarations, relating to the person's turnover of the goods in accordance with whichever of regulation 43AAC or 43AAD was applicable.

(2) The person may, on or before 15 September in the next financial year, give the Secretary, in writing:

(a) a notice stating the reasons why the person was not able to give the Secretary the declaration, or declarations, in accordance with whichever of regulation 43AAC or 43AAD was applicable for the relevant financial year; and

(b) a declaration stating that the person's turnover of the goods for the relevant financial year was of low value; and

(c) if the relevant financial year is the year commencing on 1 July 2015—a declaration in accordance with whichever of paragraph 43AAC(3)(d), (4)(d), (5)(d), (5A)(e) or (5B)(e) was applicable.

Note: A person may commit an offence if the person provides false or misleading information or documents (see sections 137.1 and 137.2 of the *Criminal Code*).

(3) The documents given under subregulation (2) must be accompanied by the fee payable.

(4) The person is exempt from liability to pay the charge for the relevant financial year if the person gives the Secretary, on or before 15 September in the next financial year:

(a) the notice referred to in paragraph (2)(a); and

(b) the declaration referred to in paragraph (2)(b); and

(c) if the relevant financial year is the year commencing on 1 July 2015—the declaration referred to in paragraph (2)(c); and

(d) the fee referred to in subregulation (3).

(5) If the person is exempt from liability to pay the charge for the relevant financial year under subregulation (4), the Secretary must give the person a written notice stating that the person is exempt from liability to pay the charge for the relevant financial year.

(6) If the person gives the Secretary documents other than in accordance with subregulation (2), or the documents were not accompanied by the fee referred to in subregulation (3), the Secretary must give the person a written notice that:

(a) states that the person is liable to pay the charge for the relevant financial year; and

(b) states the reason why the person is not exempt from liability to pay the charge for the relevant financial year, being whichever of the following is applicable in the circumstances:

(i) the person did not give the documents to the Secretary by the required date;

(ii) one or more of the documents given was not in accordance with paragraph (2)(a) or (b) or, if applicable, paragraph (2)(c);

(iii) the documents were not accompanied by the correct fee; and

(c) specifies the date on which the charge for the relevant financial year becomes payable.

43AAF Person may notify Secretary that turnover of goods for financial year will not be of low value

(1) This regulation applies in relation to the following:

(a) therapeutic goods that are registered, listed or included in the Register at any time in a financial year commencing on or after 1 July 2015 (the ***current financial year***) if the registration, listing or inclusion commenced in the current financial year;

(b) therapeutic goods (other than a biological) that are registered, listed or included in the Register at any time in a financial year commencing on or after 1 July 2015 (the ***current financial year***) if the person in relation to whom the goods are registered, listed or included in the Register was exempt from liability to pay an annual registration charge, annual listing charge or annual charge for inclusion in the Register in respect of the goods for the immediately preceding financial year;

(c) a biological that is included in the Register at any time in a financial year commencing on or after 1 July 2016 (the ***current financial year***) if the person in relation to whom the biological is included in the Register was exempt from liability to pay an annual charge for inclusion of the biological in the Register for the immediately preceding financial year.

(2) If the person in relation to whom the goods are registered, listed or included in the Register becomes aware during the current financial year that the person's turnover of the goods for that year will not be of low value, the person may notify the Secretary, in a form or a manner approved by the Secretary, of that fact.

(3) As soon as practicable after receiving a notification from a person under subregulation (2), the Secretary must give the person a written notice that specifies the date on which the charge for the current financial year becomes payable.

Note: If the registration, listing or inclusion in the Register of the goods commenced in the current financial year, the date must be the last day of the month commencing after the month in which the notification under subregulation (2) was given (see paragraph 43AAB(1)(a)).

43AAG Secretary may notify person that annual charge is payable if turnover is not of low value

Goods entered in Register at any time in 2015-16 financial year

(1) If:

(a) therapeutic goods are registered, listed or included in the Register at any time in the financial year commencing on 1 July 2015 (the ***2015-16 financial year***); and

(b) the person in relation to whom the goods are registered, listed or included in the Register has given the Secretary, in accordance with regulation 43AAC or 43AAE, a declaration stating that the person's

turnover of the goods for the 2015-16 financial year, or for a previous financial year, was of low value; and

(c) the person has not paid an annual registration charge, annual listing charge or annual charge for inclusion in the Register in respect of the goods for the 2015-16 financial year; and

(d) the Secretary becomes aware that the person's turnover of the goods for the 2015-16 financial year, or for a previous financial year for which a declaration was given, was not of low value;

the Secretary must give the person a written notice in accordance with subregulation (2).

(2) A notice given to a person under subregulation (1) must:

(a) state that the person was not exempt from liability to pay an annual registration charge, annual listing charge or annual charge for inclusion in the Register in respect of the goods:

(i) for the 2015-16 financial year; or

(ii) for any later financial year for which the person did not pay an annual registration charge, annual listing charge or annual charge for inclusion in the Register in respect of the goods (other than because the charge was waived under regulation 43AAH); and

(b) specify the date on which the relevant charge, or charges, become payable.

Goods entered in Register at any time in financial year commencing on or after 1 July 2016

(3) If:

(a) therapeutic goods are registered, listed or included in the Register at any time in a financial year commencing on or after 1 July 2016 (the ***relevant financial year***); and

(b) the person in relation to whom the goods are registered, listed or included in the Register has given the Secretary, in accordance with regulation 43AAD or 43AAE, a declaration stating that the person's turnover of the goods for the relevant financial year was of low value; and

(c) the person has not paid an annual registration charge, annual listing charge or annual charge for inclusion in the Register in respect of the goods for the relevant financial year; and

(d) the Secretary becomes aware that the person's turnover of the goods for the relevant financial year was not of low value;

the Secretary must give the person a written notice in accordance with subregulation (4).

(4) A notice given to a person under subregulation (3) must:

(a) state that the person was not exempt from liability to pay an annual registration charge, annual listing charge or annual charge for inclusion in the Register in respect of the goods:

(i) for the relevant financial year; or

(ii) for any later financial year for which the person did not pay an annual registration charge, annual listing charge or annual charge for inclusion in the Register in respect of the goods (other than because the charge was waived under regulation 43AAH); and

(b) specify the date on which the relevant charge, or charges, become payable.

Subdivision 2A—Exemption from liability to pay annual charge—IVD devices

43AAGA Purpose of this Subdivision

For section 44A of the Act, this Subdivision makes provision for and in relation to exempting a person in relation to whom an IVD device is included in the Register at any time in a financial year from liability to pay an annual charge for inclusion in the Register in respect of the device for the financial year, if the person's turnover of the device for the financial year is of low value.

43AAGB Exemption from liability to pay annual charge—2017-18 financial year

Inclusion of IVD device in Register commencing in 2017-18 financial year

(1) A person in relation to whom an IVD device is included in the Register at any time in the financial year commencing 1 July 2017 (the ***2017-18 financial year***) is exempt from liability to pay an annual charge for inclusion in the Register in respect of the device for the 2017-18 financial year if:

(a) the inclusion of the device in the Register commenced in the 2017-18 financial year; and

(b) the person's turnover of the device for the 2017-18 financial year is of low value; and

(c) the person gives the Secretary, on or before 22 July 2018, a declaration, in a form or a manner approved by the Secretary, stating that the person's turnover of the device for the 2017-18 financial year was of low value.

Inclusion of IVD device in Register on or before 30 June 2017

(2) A person in relation to whom an IVD device is included in the Register on or before 30 June 2017 is exempt from liability to pay an annual charge for inclusion in the Register in respect of the device for the 2017-18 financial year if:

(a) the inclusion of the device in the Register commenced on or before 30 June 2017; and

(b) the person's turnover of the device for the financial year commencing on 1 July 2016 (the ***2016-17 financial year***) is of low value; and

(c) the person gives the Secretary, on or before 22 July 2017, a declaration, in a form or a manner approved by the Secretary, stating that the person's turnover of the device for the 2016-17 financial year was of low value; and

(d) the person's turnover of the device for the 2017-18 financial year was of low value; and

(e) the person gives the Secretary, on or before 22 July 2018, a declaration, in a form or a manner approved by the Secretary, stating that the person's turnover of the device for the 2017-18 financial year was of low value.

Note 1: See regulation 43AAA for the meaning of ***turnover*** and when turnover is of low value.

Note 2: A person may commit an offence if the person provides false or misleading information or documents (see sections 137.1 and 137.2 of the *Criminal Code*).

Note 3: If a person is not exempt from liability to pay an annual charge for the 2017-18 financial year only because the person did not give the Secretary the declaration, or declarations, relating to turnover in accordance with this regulation, the person may be exempt from liability to pay the charge for the 2017-18 financial year under regulation 43AAGD.

Note 4: If a person becomes aware during the 2017-18 financial year that the person's turnover of the device for that year will not be of low value, the person may notify the Secretary of that fact under regulation 43AAGE.

Note 5: If the Secretary becomes aware that a person's turnover of the device, for a financial year for which a declaration was given under this regulation, was not of low value, the Secretary may, under regulation 43AAGF, notify the person that the person is liable to pay the charge for the 2017-18 financial year.

43AAGC Exemption from liability to pay annual charge—financial years commencing on or after 1 July 2018

A person in relation to whom an IVD device is included in the Register at any time in a financial year commencing on or after 1 July 2018 (the ***current financial year***) is exempt from liability to pay an annual charge for inclusion in the Register in respect of the device for the current financial year if the following requirements are met:

(a) either:
  (i) the person was exempt from liability to pay the charge in respect of the device for the immediately preceding financial year; or
  (ii) the inclusion in the Register of the device commenced in the current financial year;

(b) the person's turnover of the device for the current financial year is of low value;

(c) the person gives the Secretary, on or before 22 July of the next financial year, a declaration, in a form or a manner approved by the Secretary, stating that the person's turnover of the device for the current financial year was of low value.

Note 1: See regulation 43AAA for the meaning of ***turnover*** and when turnover is of low value.

Note 2: A person may commit an offence if the person provides false or misleading information or documents (see sections 137.1 and 137.2 of the *Criminal Code*).

Note 3: If a person is not exempt from liability to pay an annual charge for the current financial year only because the person did not give the Secretary the declaration relating to turnover in accordance with this regulation, the person may be exempt from liability to pay the charge for the current financial year under regulation 43AAGD.

Note 4: If a person becomes aware during the current financial year that the person's turnover of the device for that year will not be of low value, the person may notify the Secretary of that fact under regulation 43AAGE.

Note 5: If the Secretary becomes aware that a person's turnover of the device for the current financial year was not of low value, the Secretary may, under regulation 43AAGF, notify the person that the person is liable to pay the charge for the current financial year.

43AAGD Exemption from liability to pay annual charge—late notice that turnover was of low value

(1) This regulation applies if a person would have been exempt from liability to pay an annual charge for inclusion in the Register in respect of an IVD device for a financial year commencing on or after 1 July 2017 (the ***relevant financial year***), except that the person did not give the Secretary a declaration, or declarations, relating to the person's turnover of the device in accordance with whichever of regulation 43AAGB or 43AAGC was applicable.

(2) The person may, on or before 15 September in the next financial year, give the Secretary, in writing:

(a) a notice stating the reasons why the person was not able to give the Secretary the declaration, or declarations, in accordance with whichever of regulation 43AAGB or 43AAGC was applicable for the relevant financial year; and

(b) a declaration stating that the person's turnover of the device for the relevant financial year was of low value; and

(c) if the relevant financial year is the year commencing on 1 July 2017—a declaration in accordance with paragraph 43AAGB(2)(c).

Note: A person may commit an offence if the person provides false or misleading information or documents (see sections 137.1 and 137.2 of the *Criminal Code*).

(3) The documents given under subregulation (2) must be accompanied by the fee payable.

(4) The person is exempt from liability to pay the charge for the relevant financial year if the person gives the Secretary, on or before 15 September in the next financial year:

(a) the notice referred to in paragraph (2)(a); and

(b) the declaration referred to in paragraph (2)(b); and

(c) if the relevant financial year is the year commencing on 1 July 2017—the declaration referred to in paragraph (2)(c); and

(d) the fee referred to in subregulation (3).

(5) If the person is exempt from liability to pay the charge for the relevant financial year under subregulation (4), the Secretary must give the person a written notice stating that the person is exempt from liability to pay the charge for the relevant financial year.

(6) If the person gives the Secretary documents other than in accordance with subregulation (2), or the documents were not accompanied by the fee referred to in subregulation (3), the Secretary must give the person a written notice that:

(a) states that the person is liable to pay the charge for the relevant financial year; and

(b) states the reason why the person is not exempt from liability to pay the charge for the relevant financial year, being whichever of the following is applicable in the circumstances:
  (i) the person did not give the documents to the Secretary by the required date;
  (ii) one or more of the documents given was not in accordance with paragraph (2)(a) or (b) or, if applicable, paragraph (2)(c);
  (iii) the documents were not accompanied by the correct fee; and
(c) specifies the date on which the charge for the relevant financial year becomes payable.

43AAGE Person may notify Secretary that turnover of IVD device for financial year will not be of low value

(1) This regulation applies in relation to the following:
  (a) an IVD device that is included in the Register at any time in a financial year commencing on or after 1 July 2017 (the ***current financial year***) if the inclusion commenced in the current financial year;
  (b) an IVD device that is included in the Register at any time in a financial year commencing on or after 1 July 2017 (the ***current financial year***) if the person in relation to whom the device is included in the Register was exempt from liability to pay an annual charge for inclusion in the Register in respect of the device for the immediately preceding financial year.

(2) If the person in relation to whom the device is included in the Register becomes aware during the current financial year that the person's turnover of the device for that year will not be of low value, the person may notify the Secretary, in a form or a manner approved by the Secretary, of that fact.

(3) As soon as practicable after receiving a notification from a person under subregulation (2), the Secretary must give the person a written notice that specifies the date on which the charge for the current financial year becomes payable.

Note: If the inclusion in the Register of the device commenced in the current financial year, the date must be the last day of the month commencing after the month in which the notification under subregulation (2) was given (see paragraph 43AAB(1)(a)).

43AAGF Secretary may notify person that annual charge is payable if turnover is not of low value

IVD device entered in Register at any time in 2017-18 financial year

(1) If:
  (a) an IVD device is included in the Register at any time in the financial year commencing on 1 July 2017 (the ***2017-18 financial year***); and
  (b) the person in relation to whom the device is included in the Register has given the Secretary, in accordance with regulation 43AAGB or 43AAGD, a declaration stating that the person's turnover of the device for the

2017-18 financial year, or for a previous financial year, was of low value; and

(c) the person has not paid an annual charge for inclusion in the Register in respect of the device for the 2017-18 financial year; and

(d) the Secretary becomes aware that the person's turnover of the device for the 2017-18 financial year, or for a previous financial year for which a declaration was given, was not of low value;

the Secretary must give the person a written notice in accordance with subregulation (2).

(2) A notice given to a person under subregulation (1) must:

(a) state that the person was not exempt from liability to pay an annual charge for inclusion in the Register in respect of the device:

(i) for the 2017-18 financial year; or

(ii) for any later financial year for which the person did not pay an annual charge for inclusion in the Register in respect of the device (other than because the charge was waived under regulation 43AAH); and

(b) specify the date on which the relevant charge, or charges, become payable.

IVD device entered in Register at any time in financial year commencing on or after 1 July 2018

(3) If:

(a) an IVD device is included in the Register at any time in a financial year commencing on or after 1 July 2018 (the ***relevant financial year***); and

(b) the person in relation to whom the device is included in the Register has given the Secretary, in accordance with regulation 43AAGC or 43AAGD, a declaration stating that the person's turnover of the device for the relevant financial year was of low value; and

(c) the person has not paid an annual charge for inclusion in the Register in respect of the device for the relevant financial year; and

(d) the Secretary becomes aware that the person's turnover of the device for the relevant financial year was not of low value;

the Secretary must give the person a written notice in accordance with subregulation (4).

(4) A notice given to a person under subregulation (3) must:

(a) state that the person was not exempt from liability to pay an annual charge for inclusion in the Register in respect of the device:

(i) for the relevant financial year; or

(ii) for any later financial year for which the person did not pay an annual charge for inclusion in the Register in respect of the device (other than because the charge was waived under regulation 43AAH); and

(b) specify the date on which the relevant charge, or charges, become payable.

Subdivision 2B—Waiver of certain annual charges

43AAGG Purpose of Subdivision

For the purposes of paragraph 63(3)(b) of the Act, this Subdivision makes provision for and in relation to waiving an annual registration charge, annual listing charge or annual charge for inclusion in the Register in respect of therapeutic goods for a financial year in certain circumstances.

43AAH Waiver of certain annual charges

Scope

(1) This regulation applies in relation to a person who is liable to pay:
  (a) an annual registration charge for registered goods that are medicines; or
  (b) an annual charge for inclusion in the Register for a financial year of:
    (i) a biological; or
    (ii) a medical device that is classified under the *Therapeutic Goods (Medical Devices) Regulations 2002* as Class IIa or higher; or
    (iii) an IVD medical device that is classified under the *Therapeutic Goods (Medical Devices) Regulations 2002* as Class 2 or higher.

Application for waiver of charge

(2) The person may apply to the Secretary, in writing, for the charge to be waived for a financial year.

(3) An application under subregulation (2) in relation to particular therapeutic goods and a financial year (the ***relevant financial year***) must:
  (a) be made:
    (i) if the registration or inclusion in the Register of the goods commenced in the relevant financial year—before 31 December in the next financial year; and
    (ii) in any other case—at any time during the relevant financial year; and
  (b) be accompanied by information in support of the application that addresses the matters referred to subregulations (7) and (8).

Note 1: No application fee is payable.

Note 2: A person may commit an offence if the person provides false or misleading information or documents (see sections 137.1 and 137.2 of the *Criminal Code*).

Decision by Secretary

(4) Within 60 days after receiving an application in accordance with subregulation (3) to waive a charge for a financial year, the Secretary must decide:
  (a) to waive the charge for the financial year; or
  (b) to refuse to waive the charge for the financial year.

(5) In considering the application, the Secretary:
  (a) must take into account the information referred to in paragraph (3)(b); and
  (b) must not take into account any other information provided by, or on behalf of, the applicant after the making of the application, other than information provided in response to a request from the Secretary.

(6) Paragraph (5)(a) does not otherwise limit the information the Secretary may take into account in considering the application.

(7) The Secretary may decide to waive the charge for a financial year only if the Secretary is satisfied that:
  (a) the goods to which the charge relates are registered or included in the Register at the time the Secretary is considering the application; and
  (b) it is in the interest of public health for the entry in relation to the goods to remain on the Register; and
  (c) it would not be financially viable for the entry in relation to the goods to remain on the Register if the person in relation to whom the goods are entered in the Register were required to pay the charge for that financial year.

(8) For the purpose of considering whether it is in the interest of public health for the entry in relation to the goods to which the charge relates to remain on the Register, the Secretary must take into account the following matters:
  (a) the population who use the goods;
  (b) the clinical needs of the population who use the goods and the reasonable availability of alternatives to the goods for that population;
  (c) any health risks to the population who use the goods that may be associated with:
    (i) obtaining the goods through alternative means; or
    (ii) the use of alternative goods;
  (d) the likelihood of the goods being available through alternative means to the population who use the goods if the person in relation to whom the goods are entered in the Register were to request the Secretary to cancel the entry.

(9) The Secretary may take into account any other matter the Secretary considers relevant for the purpose of considering the matter referred to in subregulation (8).

Notice of decision

(10) As soon as practicable after making a decision under subregulation (4), the Secretary must give written notice of the decision to the applicant.

(11) If the decision is to refuse to waive the charge for the financial year, the notice under subregulation (10) must:
  (a) set out the reasons for the decision; and
  (b) specify the date on which the charge for the financial year becomes payable.

Period during which decision has effect

(12) If the Secretary decides to waive the charge for the financial year, the decision has effect unless, before the end of the financial year, the person in relation to whom the goods concerned are entered in the Register requests the Secretary to cancel the entry in relation to the goods.

(13) If a decision by the Secretary to waive a charge for a financial year in respect of therapeutic goods ceases to have effect because the entry in relation to the goods in the Register is cancelled at the request of the person in relation to whom the goods were entered in the Register, the Secretary must give the person a written notice that specifies the date on which the charge for the financial year becomes payable.

Subdivision 3—Charges for licensing

43AAJ Licensing charge—reduction in certain circumstances

(1) This regulation applies to a person if:
  (a) the person is required to hold a licence under Part 3-3 of the Act; and
  (b) the person's turnover of therapeutic goods is not more than $111,065 in a financial year.

(2) The annual charge payable by the person for a licence in force at any time during the financial year, other than a licence for the manufacture of human blood and blood components, is 50% of the amount otherwise payable under subsection 7(5) of the *Therapeutic Goods (Charges) Regulations 2018* for the licence.

Division 2—Fees and costs

43 Fees

(1) Subject to the other provisions of this Part:

(a) the fee mentioned in column 3 of an item in Part 2 or 3 of Schedule 9 is prescribed for the matter that, for that fee, is mentioned in column 2 of the item; and

(aa) the fee mentioned in column 2 of an item in Part 4 of Schedule 9 is prescribed for the matter that, for that fee, is mentioned in column 1 of the item; and

(b) the fee mentioned in column 3 of an item in Part 2 of Schedule 9A is prescribed for the matter that, for that fee, is mentioned in column 2 of the item.

(2) If, but for this subregulation, more than one fee referred to in item 9 in Part 2 of Schedule 9 would otherwise apply in relation to:

(a) an application to carry out steps in the manufacture of therapeutic goods at particular premises; or

(b) the inspection of licensed manufacturing premises for the purposes of section 40 of the Act;

the fee that is the greatest applicable fee is the only fee that applies in respect of that application or inspection.

43A When is no application fee payable?

Certain applications to transfer entries of kinds of medical devices

(2) The applicable fee under item 2 or 3 in Part 2 of Schedule 9 for an application to transfer an entry of a kind of medical device from the part of the Register for medical devices to the part of the Register for registered goods, or the part of the Register for listed goods, is not payable if the device ceases to be a medical device because of a declaration in force under subsection 41BD(3) of the Act.

Certain applications for the listing of medicines

(4) The fee under paragraph (b) of item 3 of the table in Part 2 of Schedule 9 for an application for the listing of medicine is not payable if:

(a) the application is for the listing of medicine (the ***relisted medicine***) under section 26A of the Act; and

(b) the sponsor of the application holds a listing for medicine (the ***existing medicine***) that is the same as the relisted medicine, disregarding differences in relation to indications; and

(c) the relisted medicine, if listed, would form part of the same gazetted therapeutic goods group as the existing medicine; and

(d) the application is made before the end of 5 March 2021.

43AA Fee for evaluation—refund in certain circumstances

If:

(a) an applicant has paid the whole of the evaluation fee payable under Part 2 of Schedule 9 for an evaluation of an application under subsection 9D(3) of the Act to which regulation 16D applies; and

(b) the Secretary has notified the applicant of the decision; and

(c) the notification did not occur within the period specified for the application in subregulation 16D(3);

then 25% of the evaluation fee must be refunded to the applicant.

43AB Circumstances in which inspection fee covered by annual charge

(1) A fee is not payable in accordance with item 9AB in Part 2 of Schedule 9 for an inspection covered by the annual charge for a licence to manufacture the therapeutic goods mentioned in that item.

(2) An inspection is covered by the annual charge for a licence to manufacture the therapeutic goods if no more than 2 prior inspections have been carried out at the metropolitan site, identified in the licence, within the period of 3 years immediately preceding the relevant inspection.

(3) In this regulation:

inspection means an inspection in relation to a metropolitan site.

43AC Refund of fees where no evaluation undertaken—registered OTC medicines

(1) This regulation applies if:

(a) a person makes an application of a kind mentioned in item 6 of the table in Part 3 of Schedule 9; and

(b) the person has paid the application fee required under that item in respect of the application; and

(c) an evaluation of documentation in respect of the application is not undertaken.

(2) The Secretary must refund to the person the following amount:

(a) for a C2 (section 9D) application—$4,533;

(b) for a C3 (section 9D) application—$7,609;

(c) for a C4 (section 9D) application—$9,930.

43ACA Refund of fees where no evaluation undertaken—certain registered and listed medicines

(1) This regulation applies if:

(a) a person makes a request of a kind mentioned in item 1A, 1B, 2, 3 or 4 of the table in Part 4 of Schedule 9; and

(b) the person has paid the application fee required under the item in respect of the request; and

(c) an evaluation of documentation in respect of the request is not undertaken.

(2) The Secretary must refund to the person the following amount:

(aa) for an L(A)C1 (section 9D) request—$1,188;

(ab) for an L(A)C2 (section 9D) request—$8,635;

(a) for an RCMC2 (section 9D) request—$4,576;

(b) for an RCMC3 (section 9D) request—$7,167;

(c) for an RCMC4 (section 9D) request—$10,588.

43AD Fee for therapeutic goods (priority applicant) determination application—refund in certain circumstances

(1) This regulation applies if:

(a) a person applies to the Secretary under regulation 16H to designate a medicine as an orphan drug; and

(b) at the same time as, or after, applying for the designation, the person applies to the Secretary under subregulation 16Q(1) for a therapeutic goods (priority applicant) determination in relation to the medicine; and

(c) the person pays the fee prescribed in item 1B of Part 2 of Schedule 9 for applying for the determination; and

(d) after the person pays the fee, the Secretary designates the medicine as an orphan drug under regulation 16J.

(2) The Secretary must refund the fee to the person (whether or not the Secretary makes the determination).

43AE Fee for application for provisional determination relating to medicine—refund in certain circumstances

(1) This regulation applies if:

(a) a person applies to the Secretary under regulation 16H to designate a medicine as an orphan drug; and

(b) at the same time as, or after, applying for the designation, the person applies to the Secretary under subsection 22C(1) of the Act for a provisional determination in relation to the medicine; and

(c) the person pays the fee prescribed in item 1AA of the table in clause 3 of Schedule 9 for applying for the determination; and

(d) after the person pays the fee, the Secretary designates the medicine as an orphan drug under regulation 16J.

(2) The Secretary must refund the fee to the person (whether or not the Secretary makes the determination).

43AF Fee for request for variation of certain registered and listed medicines—refund in certain circumstances

If:

(a) a person (the ***applicant***) makes a request under section 9D of the Act; and

(b) the request is:

(ia) an L(A)C1 (section 9D) request; or

(ib) an L(A)C2 (section 9D) request; or

(i) an RCMC2 (section 9D) request; or

(ii) an RCMC3 (section 9D) request; or

(iii) an RCMC4 (section 9D) request; and

(c) the Secretary makes a decision on the request but not within the period specified for the request in regulation 16GG;

then 25% of the application fee must be refunded to the applicant.

44 Testing of samples—recovery of costs

If a person asks the Department to analyse a sample of goods, the costs incurred by the Department in carrying out that analysis are recoverable from that person as a debt due to the Commonwealth.

45 Waiver or reduction of fees

Reduction of evaluation fee for certain goods—supply in the interest of public health that would otherwise not be commercially viable

(1) The Secretary may reduce by 70% the amount of the evaluation fee specified in Schedule 9 that is payable in relation to the supply of therapeutic goods (other than goods of a kind mentioned in Part 1 of Schedule 10) if the supply of those goods:

(a) is in the interest of public health; and

(b) would not be commercially viable for the sponsor of the goods if the full amount of the fee were paid.

Waiver or reduction of evaluation fee for certain goods—goods with same active ingredient and common information

(2) The Secretary may waive, or reduce, an evaluation fee prescribed in Schedules 9 and 9A in relation to an application (other than an application relating to goods of a kind mentioned in Part 1 of Schedule 10) if the applicant makes another application, or other applications, in relation to therapeutic goods at the same time and the following circumstances apply:

(a) the goods to which each application relates contain the same active ingredient;

(b) the information given in support of each application has sufficient commonality, in respect of the goods, that a simultaneous evaluation of the goods may conveniently be made.

Waiver or reduction of application and evaluation fees for certain medicines—additional applications for goods with same active ingredient and common information

(3A) The Secretary may waive or reduce the application and evaluation fees specified in Schedule 9 that are payable in relation to an application if:

(a) the application is of a kind mentioned in subregulation (3B); and

(b) the applicant makes one or more additional applications of the same kind; and

(c) each application relates to goods that contain the same therapeutically active ingredient; and

(d) the information in support of each application is sufficiently common in respect of the goods to enable a simultaneous assessment of the goods to be made.

(3B) The applications are as follows:

(a) an L(A)1 application;

(b) an L(A)2 application;

(c) an L(A)3 application;

(d) an RCM1 application;

(e) an RCM2 application;

(f) an RCM3 application;

(g) an RCM4 application;

(h) an RCM5 application.

Waiver or reduction of evaluation fees for certain goods—abridged evaluation procedure

(4) The Secretary may waive, or reduce, an evaluation fee prescribed in Schedules 9 and 9A in relation to an application (other than an application relating to goods of a kind mentioned in Part 1 of Schedule 10):

(a) to register goods; or

(aa) to list goods under section 26AE of the Act; or

(b) in relation to registered goods that are a medicine—to vary the information entered in the Register; or

(c) to include goods in the part of the Register for biologicals; or

(d) for a biological included in the Register under Part 3-2A of the Act—to vary the information included in the Register;

if the Secretary has information relating to the goods that enables the evaluation procedure to be abridged.

Waiver or reduction of evaluation fees for supply of certain medicines in public health emergency—abridged evaluation procedure

(4AA) The Secretary may waive, or reduce, an evaluation fee prescribed in Schedule 9 in relation to a submission for goods of a kind mentioned in Part 1 of Schedule 10 if, in the Secretary's opinion:

(a) supply of the goods in Australia is necessary because of a public health emergency; and
(b) the waiver or reduction is necessary to enable the goods to be supplied in Australia; and
(c) the Secretary has information relating to the goods that allows the evaluation procedure to be abridged.

Reduction of application and evaluation fees for certain medicines—abridged preliminary assessment and evaluation procedure

(5) Subregulation (6) applies in relation to an application made under section 23 of the Act for the registration of a medicine if:
(a) the medicine is a product of a kind specified in Part 1 of Schedule 10; and
(b) apart from the directions for use or the dosage model, the medicine is the same as another medicine that is included in the Register; and
(c) the Secretary is satisfied that:
(i) the differences in the directions for use or the dosage model are necessary to ensure the safe use of the medicine; and
(ii) neither non-clinical nor quality data needs to be evaluated in the evaluation of the medicine for registration; and
(d) the Secretary has information relating to the medicine that enables the preliminary assessment of the application and the evaluation of the medicine for registration to be abridged.

(6) The Secretary may:
(a) reduce the application fees specified in Schedule 9 that are payable in relation to the application to $1,241; and
(b) reduce the evaluation fees specified in Schedule 9 that are payable in relation to the application to $4,954.

Fee waivers for prescription opioids

(7) The Secretary must waive a fee prescribed in Schedule 9 in relation to a request (an ***opioid reform request***) that satisfies all of the following:
(a) it is made in relation to prescription opioids that are registered goods;
(b) it is made in the period beginning on the commencement of this subregulation and ending at the end of 31 December 2021;
(c) it is made under subsection 9D(2) or (3) of the Act;
(d) it is made solely for an opioid reform purpose (see subregulation (8)) or solely for an opioid reform purpose and an associated variation of product information purpose (see subregulation (9)).

(8) For the purposes of subregulation (7), an opioid reform request is made for an opioid reform purpose if it is made:
(a) under subsection 9D(2) of the Act, to do either or both of the following:
(i) add a warning, or precaution, in relation to the goods that does not include any comparison of the goods with any other therapeutic goods by reference to quality, safety or efficacy;

(ii) reduce the class of persons for whom the goods are suitable; or

(b) under subsection 9D(3) of the Act, to introduce a smaller pack size in relation to the goods.

(9) For the purposes of subregulation (7), an opioid reform request is made for an associated variation of product information purpose if:

(a) the opioid reform request is made under subsection 9D(3) of the Act; and

(b) paragraphs 9D(3)(b) to (c) of the Act are satisfied in relation to the request; and

(c) the request is made for the purpose of varying product information in relation to the prescription opioids so that the product information is in the form approved under section 7D of the Act in relation to the prescription opioids.

Waiver of application and registration fees for designated orphan drugs

(12) The Secretary must waive the following fees:

(a) a fee that would have been payable, but for this subregulation, as part of an application under subsection 22C(1) of the Act relating to a medicine that is a designated orphan drug;

(b) a fee that would have been payable, but for this subregulation, as part of an application under subsection 22E(3) of the Act relating to a medicine that is a designated orphan drug;

(c) a fee that would have been payable, but for this subregulation, as part of the registration of a designated orphan drug;

(d) a fee that would have been payable, but for this subregulation, for applying for a therapeutic goods (priority applicant) determination in relation to a medicine that is a designated orphan drug.

Fee waiver for requests to vary product information for medicine

(13) The Secretary must waive a fee prescribed in Schedule 9 in relation to a request that a person makes under subsection 9D(3) of the Act if:

(a) the request is in relation to therapeutic goods that are registered; and

(b) the therapeutic goods are medicine; and

(c) paragraphs 9D(3)(b) to (c) of the Act are satisfied in relation to the request; and

(d) the request is made solely for the purpose of varying product information in relation to the medicine so that the product information is in the form approved under section 7D of the Act in relation to the medicine; and

(e) the request is made in the period beginning on 1 January 2020 and ending at the end of 31 December 2020.

45AA Payment of fees in instalments

(1) Subject to subregulation (7), the Secretary may allow the amount of a fee payable under item 4, 5, 6, 10 or 11 in Schedule 9A to be paid in instalments, if:

(a) the applicant has applied in writing to pay the amount in instalments; and

(b) the amount payable exceeds $10,000; and
(c) the Secretary is reasonably satisfied that the applicant will experience financial hardship if that amount is paid before the commencement of the evaluation to which the fee relates; and
(d) any information or material to which subregulation (3) applies has been provided to the Secretary.

(2) An application under subregulation (1) must:
(a) state the reasons why payment of the full amount of the fee before the evaluation commences will cause financial hardship to the applicant; and
(b) have with it documents or other material in support of the statement.

(3) If the Secretary reasonably requires information or material in addition to the documents or material referred to in paragraph 2(b), the Secretary may require the applicant to provide the information or material to the Secretary.

(4) If the Secretary approves an application under subregulation (1):
(a) 50% of the fee is due for payment before the commencement of the evaluation of the application; and
(b) 25% of the fee is due for payment at the end of 1 month after the day on which the amount referred to in paragraph (a) is due for payment; and
(c) the remaining 25% is due for payment:
(i) if the application for evaluation is withdrawn—at the time of withdrawal; or
(ii) if the Secretary refuses the application to include the biological in the Register—when the applicant is notified under section 32DG of the Act; or
(iii) if the evaluation is completed—before the biological is included in the Register.

(5) If:
(a) the Secretary approves an application under subregulation (1); and
(b) any amount of the fee payable by the applicant is not paid when it becomes due for payment;
the balance of the fee becomes due for payment.

(6) If the Secretary receives an application under subregulation (1), he or she must:
(a) give notice in writing to the applicant within 30 days of receiving the application whether the application has been approved; and
(b) if the application is approved—include with the notice information about the amounts of the instalments and when the instalments are due for payment.

(7) This regulation does not apply while another evaluation fee, or an assessment fee payable under section 41LA of the Act (or part of either of those kinds of fee), that is due for payment by the applicant is unpaid.

Part 8—Miscellaneous

46A Delegation under the Act

(1) For paragraph 57(1)(c) of the Act, the secondment of a person employed by a national therapeutic goods regulatory authority of another country to a position in the Department is declared to be an appointment the occupant or holder of which may be a delegate under section 57 of the Act.

(2) For the purposes of subsection 57(8) of the Act, the following positions are prescribed:
- (a) an SES Band 1, 2 or 3 position;
- (b) each position classified as a Medical Officer Class 3, 4, 5 or 6;
- (c) an Executive Level 1 or 2 position.

46 Release of information

(1) In this regulation, ***therapeutic goods information*** has the same meaning as in section 61 of the Act.

(2) For the purposes of subsection 61(6) of the Act, the Secretary may release to a person, on application by the person, therapeutic goods information in respect of an entry in the Register, being therapeutic goods information of the following kinds:
- (a) whether the goods are included in the Register and, if so:
  - (i) the registration number, listing number, biological number or device number of the goods; and
  - (ii) the date when the goods were registered, listed or included in the Register; and
  - (iii) the class in which the goods are included in the Register;
- (b) the name of the goods and the name and address of the sponsor of the goods;
- (c) if any ingredient in, or component of, the goods is derived from an animal, the type of the animal;
- (d) if the goods are supplied in a sterile state, the type of sterilisation used;
- (e) if the goods are medicines or biologicals, medical devices that contain medicines or biologicals, or medical devices that incorporate, or are intended to incorporate, as an integral part, a medicine or biological that is intended to act on a patient in a way that is ancillary to the device:
  - (i) the quantity of goods to be in the primary pack; and
  - (ii) the entry relating to the goods in the Poisons Standard; and
  - (iii) the indications for the goods; and
  - (iv) the dosage form of the goods and their physical appearance; and
  - (v) the names and quantities of therapeutically active substances in the goods; and

(vi) the presence or absence of any specific excipient in the goods; and
(vii) the routes of administration of the goods; and
(viii) the type of container in which the goods are to be packed; and
(f) if the goods are a kind of medical device:
(i) the intended purpose of the device; and
(ii) the device nomenclature system code specified for the device under subsection 41BE(3) of the Act; and
(iii) the medical device classification applying to the device;
(g) whether the goods are a designated orphan drug;
(h) if the goods are a biological—which class.

(4) For the purposes of subsection 61(6) of the Act, the Secretary may release therapeutic goods information of a kind that a court, tribunal, authority, or other body or person may require to be given or produced under a law of the Commonwealth, or of a State or Territory.

47 Delegation—powers and functions under these Regulations

(1) The Secretary may delegate a power or function of the Secretary under these Regulations to an officer of the Department.

(2) The delegation must be by instrument signed by the Secretary.

47A Delegation—powers under paragraphs 19(1)(a), 32CK(1)(d) and 41HB(1)(d) of the Act

(1) In this regulation:

delegation means a delegation, under subsection 57(3) of the Act, of powers of the Secretary under any of the following provisions of the Act:
(a) paragraph 19(1)(a), relating to specified therapeutic goods;
(b) paragraph 32CK(1)(d), relating to specified biologicals;
(c) paragraph 41HB(1)(d), relating to a specified medical device or a kind of medical device.

(2) A delegation may only be to a person who:
(a) is a medical practitioner registered in a State or Territory and employed by an institution that has an ethics committee; and
(b) subject to subregulation (3), is proposed by the medical superintendent or, if there is no medical superintendent, the person occupying a position comparable to that of medical superintendent, of the institution, as a person to be a delegate under subsection 57(3) of the Act.

(3) If:
(a) a person proposes another person under paragraph (2)(b) as a person to be a delegate; and
(b) that other person becomes a delegate;

the first-mentioned person must supervise each approval that the delegate grants under the delegation.

(4) A delegation must describe the person or class of persons to be treated with the therapeutic goods, biologicals or devices to which the delegation relates.

(5) A delegation may be made for the purpose of allowing the delegate to grant an approval in relation to:

(a) a particular item of therapeutic goods; or

(b) a particular class of therapeutic goods; or

(c) a particular biological; or

(d) a particular class of biologicals; or

(e) a particular medical device; or

(f) a particular kind of medical device;

for treating a specific illness or condition.

(6) A delegate may grant an approval under a delegation only if:

(a) a medical practitioner, other than the delegate, has stated in writing that the person to be treated with the biological, a kind of medical device or other therapeutic goods to which the approval relates has an illness or condition that requires treatment with the biological, medical device or other therapeutic goods; and

(b) an ethics committee has agreed to the granting of approval under paragraph 19(1)(a), 32CK(1)(d) or 41HB(1)(d) of the Act for the use, in the circumstances in which the delegate grants the approval, of the biological, kind of medical device or other therapeutic goods to which the delegation relates.

47B Provision of information concerning medicines, biologicals and medical devices

(1) The following persons must provide a report to the Secretary every 6 months:

(a) a delegate under subsection 57(3) of the Act;

(b) a person authorised under subsection 19(5), 32CM(1) or 41HC(1) of the Act to supply a medicine, biological or medical device;

(c) a sponsor of therapeutic goods in relation to which any of the following applies:

(i) an exemption under section 18, 32CA or 41HA of the Act;

(ii) an approval under section 19, 32CK or 41HB of the Act;

(iii) an authority under section 19, 32CM or 41HC of the Act.

(2) The report must be in a form approved by the Secretary.

(3) A report by a person mentioned in paragraph (1)(a) must:

(a) list each biological, kind of medical device and other item of therapeutic goods approved by the person during the period to which the report relates; and

(b) state the number of new approvals, and the number of repeat approvals, of medicines, biologicals and medical devices that the person gave during that period.

(4) A report by a person mentioned in paragraph (1)(b) must list each biological, kind of medical device and other item of therapeutic goods supplied by the person during the period to which the report relates.

(5) A report by a sponsor of therapeutic goods must:

(a) list each kind of therapeutic goods supplied by the sponsor during the period to which the report relates; and

(b) state the number of times therapeutic goods have been supplied to health practitioners, and the quantity supplied:

(i) to which section 18, subsection 32CA(2) or section 41HA of the Act applies; and

(ii) to which paragraph 19(1)(a), 32CK(1)(d) or 41HB(1)(d) of the Act applies; and

(iii) to which paragraph 19(1)(b), 32CK(1)(e) or 41HB(1)(e) of the Act applies; and

(iv) to which subsection 19(5), 32CM(1) or 41HC(1) of the Act applies; and

(v) to which rules made under subsection 19(7A), 32CM(7A) or 41HC(6) of the Act apply.

48 Review of decisions

Definitions

(1) In this regulation:

decision has the same meaning as in the *Administrative Appeals Tribunal Act 1975*.

eligible person, in relation to an initial decision specified in column 1 of an item of the following table, means a person specified in column 2 of the item.

Eligible persons in relation to initial decisions

Item	Column 1 Initial decision	Column 2 Eligible person
1	initial decision not covered by another item of this table	a person whose interests are affected by the initial decision
2	decision to refuse to make a therapeutic goods (priority applicant) determination or biologicals (priority applicant) determination	the person who applied for the determination
3	decision to revoke a therapeutic goods (priority applicant) determination or biologicals (priority	the priority applicant specified in the determination

Eligible persons in relation to initial decisions		
Item	**Column 1** **Initial decision**	**Column 2** **Eligible person**
	applicant) determination	
4	decision under regulation 10JE or 10JF to refuse to approve an application for approval	the person who applied for the approval
5	decision under regulation 10JE or 10JF to revoke or vary an approval of a specified person to import or export mercury	the person specified in the approval
6	decision covered by subregulation (1AB)	the sponsor concerned

initial decision means a decision of the Secretary under any of the following provisions:

(ca) subregulation 10C(3), (5) or (6);

(e) subparagraph 16J(1)(b)(ii);

(ea) paragraph 16L(3)(b);

(eb) paragraph 16M(1)(b);

(ec) subparagraph 16R(1)(b)(ii);

(ed) subregulation 16T(1);

(ee) subparagraph 16W(1)(b)(ii);

(ef) subregulation 16Y(1);

(f) subregulation 22(8);

(fa) paragraph 43AAH(4)(b);

(g) regulation 45;

(h) regulation 45AA.

Note: See also subregulations (1AA) and (1AB) of this regulation.

reviewable decision means a decision of the Minister under subregulation (3).

(1AA) Each of the following decisions of the Secretary under regulation 10JE or 10JF (about importing or exporting mercury) is an ***initial decision***:

(a) a decision to refuse to approve an application for approval;

(b) a decision to revoke or vary an approval.

(1AB) Each of the following decisions of the Secretary is an ***initial decision***:

(a) a decision to refuse to agree to a notification covered by paragraph (a) of column 3 of item 3 of the table in Schedule 5A being given before the end of a period nominated by the sponsor concerned;

(b) a decision to refuse to agree to a notification covered by paragraph (ha) of column 3 of item 3 of the table in Schedule 5A being given before the end of a period nominated by the sponsor concerned.

Delegation

(1A) The Minister may, by signed instrument, delegate a power or function of the Minister under this regulation to an officer of the Department.

Requests for reconsideration of initial decisions

(2) An eligible person in relation to an initial decision may request the Minister to reconsider the decision by notice in writing given to the Minister within 90 days after the decision first comes to the person's notice.

(2A) A request under subregulation (2) may be accompanied by information in support of the request.

Reconsideration of initial decisions

(3) The Minister must reconsider the initial decision as soon as practicable after receiving a request under subregulation (2), and may:

(a) confirm the initial decision; or

(b) revoke the initial decision, or revoke that decision and make a decision in substitution for the initial decision.

(3A) In reconsidering the initial decision:

(a) the Minister must take into account any information referred to in subregulation (2A); and

(b) the Minister must not take into account any other information provided by, or on behalf of, the person after the making of the request, other than information provided in response to a request from the Minister.

(3B) Paragraph (3A)(a) does not otherwise limit the information the Minister may take into account in reconsidering the initial decision.

(3C) If, under paragraph (3)(b), the Minister revokes an initial decision and makes a decision in substitution for the initial decision, then the substituted decision:

(a) is taken to be a decision of the Secretary (except for the purpose of any review of the substituted decision); and

(b) has effect, or is taken to have had effect, on and from the date determined by the Minister.

(4) If a person who has made a request under subregulation (2) does not receive notice of the decision of the Minister on reconsideration within 60 days of the making of the request, the Minister is to be taken to have confirmed the original decision.

(5) After reconsideration of an initial decision, the Minister must give the applicant a notice in writing stating the result of the reconsideration and that the applicant may, except where subsection 28(4) of the *Administrative Appeals Tribunal Act 1975* applies, apply for a statement setting out the reasons for the decision on reconsideration and may, subject to that Act, make an application to the Administrative Appeals Tribunal for review of that decision.

Notices about right to seek reconsideration of initial decisions

(6) If written notice of the making of an initial decision is given to a person who is an eligible person in relation to the decision, the notice is to include a statement to the effect that the person may:

(a) seek a reconsideration of the decision under this regulation; and

(b) subject to the *Administrative Appeals Tribunal Act 1975*, if the person is dissatisfied with the decision upon reconsideration, make an application to the Administrative Appeals Tribunal for review of that decision.

Failure to comply with subregulations (5) and (6) does not affect decisions

(7) Any failure to comply with the requirements of subregulation (5) or (6) in relation to a decision does not affect the validity of the decision.

Applications for review of reviewable decisions

(8) An application may be made to the Administrative Appeals Tribunal for review of a reviewable decision.

Part 9—Transitional

Division 1—Transitional provisions relating to the Therapeutic Goods Amendment Regulations 2010 (No. 1)

48A Definitions

In this Division:

2010 Amendment Regulations means the *Therapeutic Goods Amendment Regulations 2010 (No. 1)*.

finally determined has the same meaning as in Division 11.1 of Part 11 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

transitional device has the same meaning as in Division 11.1 of Part 11 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

transition day, for a transitional device, has the same meaning as in Division 11.1 of Part 11 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

48B Application of 2010 Amendment Regulations

(1) The amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to a transitional device on and after the transition day for the device.

(2) However, to avoid doubt, if:

(a) a transitional device was included in the Register under Chapter 4 of the Act before 1 July 2014; or

(b) an effective application for including a transitional device in the Register under Chapter 4 of the Act was made before 1 July 2014 and the application was finally determined before that date;

the amendments made by Schedule 1 to the 2010 Amendment Regulations apply in relation to the device on and after 1 July 2014.

Division 2—Transitional provisions relating to the Therapeutic Goods Amendment Regulation 2012 (No. 3)

49 Transitional

Despite the amendments made by the *Therapeutic Goods Amendment Regulation 2012 (No. 3)*:

(a) item 7 of Part 1 of Schedule 4, as in force on 9 November 2012, continues to apply in relation to therapeutic goods already included in the part of the Register for listed goods on that date; and

(b) paragraph (g) of item 8 of Schedule 5, as in force on 9 November 2012, continues to apply in relation to goods exempt from the operation of Parts 3-2 and 3-2A of the Act on that date; and

(c) paragraph (b) of item 14 of Schedule 7, as in force on 9 November 2012, continues to apply in relation to therapeutic goods exempt from the operation of Part 3-3 of the Act on that date.

Division 3—Transitional provisions relating to the Therapeutic Goods Amendment (Registered Over the Counter Medicines) Regulation 2015

50 Application

The amendments made by the *Therapeutic Goods Amendment (Registered Over the Counter Medicines) Regulation 2015* apply in relation to applications and requests made on or after 1 January 2016.

Division 4—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (Charges Exemptions and Other Measures) Regulation 2016

51 Application

(1) The amendments made by Part 1 of Schedule 4 to the *Therapeutic Goods Legislation Amendment (Charges Exemptions and Other Measures) Regulation 2016* apply in relation to an event or change of name that occurs on or after the day that Part commences.

(2) The amendments made by items 24, 25 and 26 of Part 3 of Schedule 4 to the *Therapeutic Goods Legislation Amendment (Charges Exemptions and Other Measures) Regulation 2016* apply in relation to requests made on or after the day that Part commences.

Division 5—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (2017 Measures No. 1) Regulations 2017

52 Definitions

In this Division:

2017 Amendment Regulations means the *Therapeutic Goods Legislation Amendment (2017 Measures No. 1) Regulations 2017*.

commencement day means the day on which Part 1 of Schedule 1 to the 2017 Amendment Regulations commences.

53 Transitional—continuing application of evaluation fees for variations of permissible ingredients determinations

(1) This regulation applies if, before the commencement of Schedule 5 to the *Therapeutic Goods Amendment (2016 Measures No. 1) Act 2017*:

(a) an application had been made under subsection 26BD(1) of the Act (as in force immediately before that commencement) for a variation of a determination under subsection 26BB(1) of the Act; and

(b) no decision had been made in relation to the application; and

(c) the evaluation fee prescribed by item 7C or 7D, as the case may be, of the table in clause 3 of Schedule 9 (as in force immediately before that commencement) in relation to the application had not been paid.

(2) Despite the amendments made by Schedule 3 to the 2017 Amendment Regulations, the evaluation fee prescribed by item 7C or 7D, as the case may be, of the table in clause 3 of Schedule 9 (as in force immediately before the commencement of Schedule 5 to the *Therapeutic Goods Amendment (2016 Measures No. 1) Act 2017*) continues to apply in relation to the application.

54 Transitional—existing orphan drug designations

(1) This regulation applies if a designation by the Secretary under regulation 16J (as in force immediately before the commencement day) of a medicine, vaccine or in vivo diagnostic agent as an orphan drug was in force immediately before the commencement day.

(2) The designation continues in force for 12 months beginning on the commencement day.

55 Transitional—pending orphan drug designation applications

(1) This regulation applies if, before the commencement day:

(a) a person had applied to the Secretary under regulation 16I (as in force before the commencement day) to designate a medicine, vaccine or in vivo diagnostic agent as an orphan drug; and

(b) the application had not been finally determined.

(2) Despite the amendments made by Schedule 7 to the 2017 Amendment Regulations, Part 3B (as in force immediately before the commencement day) and regulation 48 (as in force immediately before the commencement day) continue to apply in relation to the application.

(3) If the medicine, vaccine or in vivo diagnostic agent is designated as an orphan drug under regulation 16J (as in force immediately before the commencement day):

(a) the designation:

(i) comes into force when it is made; and

(ii) remains in force for 12 months; and

(b) while the designation is in force, regulation 43AD applies in relation to the medicine, vaccine or in vivo diagnostic agent as if it had been designated as an orphan drug under regulation 16J.

56 Transitional—fee waivers in relation to certain designations

(1) This regulation applies in relation to a designation of a medicine, vaccine or in vivo diagnostic agent as an orphan drug if the designation is in force under regulation 54 or 55.

(2) The medicine, vaccine or in vivo diagnostic agent is taken to be a designated orphan drug for the purposes of the following provisions:

(a) paragraphs 45(12)(c) and (d);

(b) paragraph 46(2)(g);

(c) items 1 to 2B in Part 1 of Schedule 3;

(d) Part 3 of Schedule 3.

Division 6—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (2017 Measures No. 2) Regulations 2017

57 Definitions

In this Division:

Amendment Regulations means the *Therapeutic Goods Legislation Amendment (2017 Measures No. 2) Regulations 2017*.

commencement day means the day on which Part 3 of Schedule 4 to the Amendment Regulations commences.

58 Application—statements in relation to unapproved medicines and biologicals

The amendments of regulation 12A of these Regulations made by Part 3 of Schedule 4 to the Amendment Regulations apply in relation to a medicine or a biological given to a person on or after the commencement day.

59 Transitional—approval of form for statements

(1) This regulation applies to the approval of a form if:
  (a) the approval was made for the purposes of subparagraph 12A(2)(a)(iii) of these Regulations; and
  (b) the approval was in force immediately before the commencement day.

(2) The approval has effect, on and after the commencement day, as if it had been made for the purposes of subparagraph 12A(2)(a)(iii) of these Regulations as amended by the Amendment Regulations.

Division 7—Application and saving provisions relating to the Therapeutic Goods Legislation Amendment (2018 Measures No. 1) Regulations 2018

60 Application provisions

(1) The amendment of regulation 9B made by Schedule 1 to the *Therapeutic Goods Legislation Amendment (2018 Measures No. 1) Regulations 2018* applies in relation to the supply of goods on or after the commencement of this regulation.

(2) The amendments of regulation 16J made by Schedule 1 to the *Therapeutic Goods Legislation Amendment (2018 Measures No. 1) Regulations 2018* apply in relation to applications made under subregulation 16H(1) on or after the commencement of this regulation.

(3) The amendment of regulation 16R made by Schedule 1 to the *Therapeutic Goods Legislation Amendment (2018 Measures No. 1) Regulations 2018* applies in relation to applications made under subregulation 16Q(1) on or after the commencement of this regulation.

(4) Regulation 43AE, as inserted by Schedule 1 to the *Therapeutic Goods Legislation Amendment (2018 Measures No. 1) Regulations 2018*, applies in relation to applications made under regulation 16H on or after the commencement of this regulation.

61 Operation of Schedule 2—complementary medicines

(1) The amendments made by items 7, 14, 15, 16 and 33 of Schedule 2 to the *Therapeutic Goods Legislation Amendment (2018 Measures No. 1) Regulations 2018* apply in relation to requests or applications made on or after the commencement of this regulation.

(2) The amendments made by items 26 to 32 of Schedule 2 to the *Therapeutic Goods Legislation Amendment (2018 Measures No. 1) Regulations 2018* do not apply in relation to requests or applications made before the commencement of this regulation.

62 Saving provision

Division 5 of Part 2 and regulation 48, as in force immediately before the commencement of Part 1 of Schedule 4 to the *Therapeutic Goods Legislation Amendment (2018 Measures No. 1) Regulations 2018*, continue to apply on and after that commencement in relation to an order given under subregulation 9(1) before that commencement.

Division 8—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (Exempt Devices and Goods) Regulations 2018

63 Application of amendments

The amendments of these Regulations made by the *Therapeutic Goods Legislation Amendment (Exempt Devices and Goods) Regulations 2018* apply to a therapeutic good imported into Australia:

(a) on or after the commencement of this regulation; or

(b) during the 12 months ending immediately before that commencement, if the goods were held under the direct control of the sponsor immediately before that commencement.

Division 9—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (2018 Measures No. 2) Regulations 2018

64 Definitions

In this Division:

Amendment Regulations means the *Therapeutic Goods Legislation Amendment (2018 Measures No. 2) Regulations 2018*.

finally determined has the same meaning as in Division 11.1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

transitional goods means goods:

(a) to which paragraph 4(q) of the Therapeutic Goods (Excluded Goods) Order No. 1 of 2011 applied on 30 June 2018; and

(b) of a kind supplied in Australia on or before 30 June 2018; and

(c) to which column 2 of item 13 of Schedule 5A to these Regulations, as inserted by the Amendment Regulations, does not apply.

65 Transitional provisions—exemptions from Parts 3-2 and 3-2A of the Act

Exemptions

(1) For the purposes of subsections 18(1) and 32CA(2) of the Act, transitional goods are exempt from the operation of the following provisions of the Act:

(a) Part 3-2 (except sections 30EA, 31A and 31C to 31F);

(b) Division 4 of Part 3-2A.

(2) The exemptions mentioned in subregulation (1) are subject to compliance with the condition that, if the sponsor of the goods knows that particular information relating to an event or occurrence indicates that use of the goods as intended by the sponsor may have an unintended harmful effect, the sponsor must give the information to the Secretary within the period specified by regulation 16AB.

When exemptions cease

(3) Subregulation (1) ceases to have effect on 1 July 2019, subject to subregulations (4) and (5).

(4) If:

(a) a sponsor of transitional goods applies, on or before 30 June 2019, for registration, listing, or inclusion of the goods in the Register; and

(b) the application passes preliminary assessment on or before 30 June 2019;

subregulation (1) ceases to have effect in relation to the goods when the application is finally determined, lapses or is withdrawn, if that happens on or after 1 July 2019.

(5) If a sponsor of transitional goods applies, on or before 30 June 2019, for an approval under section 32CK in relation to the goods, subregulation (1) ceases to have effect in relation to the goods when the application is finally determined or is withdrawn, if that happens on or after 1 July 2019.

Advertising offence and civil penalty

(6) While subregulation (1) has effect in relation to transitional goods, paragraph 7(e) applies to the goods in the same way as that paragraph applies to goods mentioned in column 2 of an item in Schedule 5A.

66 Transitional provisions—exemptions from Part 3-3 of the Act

(1) For the purposes of subsection 34(1) of the Act, transitional goods are exempt from the operation of Part 3-3 of the Act.

(2) Subregulation (1) ceases to have effect on 1 July 2019, subject to subregulation (3).

(3) If, on or before 30 June 2019, each person who carries out a step in the manufacture of transitional goods applies for a licence authorising the person to carry out the step on premises referred to in the application, subregulation (1) ceases to have effect in relation to the transitional goods produced by those persons carrying out the steps on those premises when the last of those applications is finally determined or is withdrawn, if that happens on or after 1 July 2019.

Division 10—Application provisions relating to the Therapeutic Goods Legislation Amendment (2018 Measures No. 3) Regulations 2018

67 Application

The amendments of Schedules 3, 4 and 5 made by Division 1 of Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2018 Measures No. 3) Regulations 2018* apply to disinfectants after the commencement of that Division, whether or not the disinfectants were registered goods or listed goods immediately before that commencement.

Note: If disinfectants were registered goods immediately before that commencement, subregulation 10B(2) lets the persons in whose names the goods were entered in the Register immediately before that commencement apply to the Secretary:

(a) to transfer the entry for the goods to the part of the Register for listed goods; or

(b) to retain the entry in the part of the Register for registered goods.

Division 11—Application and transitional provisions relating to the Therapeutic Goods Amendment (Fees for Relisted Medicine) Regulations 2019

68 Application and transitional provisions

(1) The amendment of regulation 43A made by the *Therapeutic Goods Amendment (Fees for Relisted Medicine) Regulations 2019* applies in relation to applications made on or after 6 September 2019.

(2) If, on or after 6 September 2019 and before the commencement of the *Therapeutic Goods Amendment (Fees for Relisted Medicine) Regulations 2019*, a person:

(a) made an application for the listing of medicine in circumstances where paragraphs 43A(4)(a) to (c) were satisfied; and

(b) paid the fee under paragraph (b) of item 3 of the table in Part 2 of Schedule 9 in relation to the application;

the Secretary must, on behalf of the Commonwealth, refund to the person an amount equal to the fee paid.

Division 12—Application and transitional provisions relating to the Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019

Subdivision A—Definitions

69 Definitions

In this Division:

amending regulations means the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019*.

finally determined: an application is finally determined at the first time both the following conditions are met:

(a) a decision has been made whether or not to grant the application;

(b) there is no longer any possibility of a change in the outcome of the decision.

Subdivision B—Faecal microbiota transplant products

70 Faecal microbiota transplant products—Division 4 of Part 3-2A of the Act

Exemption

(1) For the purposes of subsection 32CA(2) of the Act, faecal microbiota transplant products are exempt from the operation of Division 4 of Part 3-2A of the Act.

(2) The exemption mentioned in subregulation (1) is subject to compliance with the condition that, if the sponsor of the faecal microbiota transplant products knows that particular information relating to an event or occurrence indicates that use of the products as intended by the sponsor may have an unintended harmful effect, the sponsor must give the information to the Secretary within the period specified by regulation 16AB.

When exemption ceases

(3) Subregulation (1) ceases to have effect on 1 July 2021, subject to subregulations (4) and (5).

(4) If a sponsor of faecal microbiota transplant products applies, on or before 30 June 2021, for inclusion of the products in the Register, subregulation (1) ceases to have effect in relation to the products when the application is finally determined, lapses or is withdrawn, if that happens on or after 1 July 2021.

(5) If a sponsor of faecal microbiota transplant products applies, on or before 30 June 2021, for an approval under section 32CK of the Act in relation to the products, subregulation (1) ceases to have effect in relation to the products when

the application is finally determined or is withdrawn, if that happens on or after 1 July 2021.

71 Faecal microbiota transplant products—Part 3-3 of the Act

(1) For the purposes of this regulation, a biological is a ***transitional biological*** if it is:

(a) a faecal microbiota transplant product; and

(b) a biological other than a Class 1 biological.

Exemption

(2) For the purposes of subsection 34(1) of the Act, transitional biologicals are exempt from the operation of Part 3-3 of the Act.

When exemption ceases

(3) Subregulation (2) ceases to have effect on 1 July 2021, subject to subregulation (4).

(4) If, on or before 30 June 2021, each person who carries out a step in the manufacture of transitional biologicals applies for a licence authorising the person to carry out the step on premises referred to in the application, subregulation (2) ceases to have effect in relation to the transitional biologicals produced by those persons carrying out the steps on those premises when the last of those applications is finally determined or is withdrawn, if that happens on or after 1 July 2021.

Subdivision C—Consumer medicine information documents

72 Consumer medicine information documents

(1) Subject to this regulation, the amendments of regulations 9A and 9B and Schedules 12 and 13 made by Schedule 6 to the amending regulations apply in relation to medicines supplied on and after 1 January 2021.

Transitional medicines

(2) Subject to subregulation (3), the amendments of regulations 9A and 9B and Schedules 12 and 13 made by Schedule 6 to the amending regulations do not apply in relation to supplies of a medicine of a kind (a ***transitional medicine***) that immediately before 1 January 2021 was a registered good.

(3) The amendments of regulations 9A and 9B and Schedules 12 and 13 made by Schedule 6 to the amending regulations apply in relation to supplies of transitional medicines on and after 1 January 2026.

Note: Subregulations 9A(1) and (1A) cover supplies of therapeutic goods that are included in the Register.

Medicines where applications not finally determined

(4) Subject to subregulation (5), the amendments of regulations 9A and 9B and Schedules 12 and 13 made by Schedule 6 to the amending regulations do not apply in relation to supplies of a medicine of a kind (a ***transitional application medicine***) while either of the following applies to the transitional application medicine:

(a) it is the subject of an application for registration that was made before 1 January 2021 and that immediately before that date was not finally determined;

(b) it is included in the Register as a result of such an application.

(5) The amendments of regulations 9A and 9B and Schedules 12 and 13 made by Schedule 6 to the amending regulations apply in relation to supplies of transitional application medicines on and after 1 January 2026.

Note: Subregulations 9A(1) and (1A) cover supplies of therapeutic goods that are included in the Register.

Subdivision D—Handling and testing of samples

73 Handling and testing of samples

The repeal and substitution of subregulation 23(2) made by Schedule 7 to the amending regulations, the amendment of paragraph 25(3)(c) made by that Schedule, subregulations 25(4) and (5) as added by that Schedule and the amendments of paragraph 27(2)(a) and of regulations 28, 29 and 30 made by that Schedule apply in relation to samples taken or delivered on or after 1 January 2020.

Subdivision E—Fee waivers and refunds for certain requests relating to prescription opioids

74 Fee waivers and refunds for certain requests relating to prescription opioids

(1) The insertion of subregulations 45(7) to (9) by Schedule 8 to the amending regulations applies in relation to requests made on or after the commencement of those subregulations.

(2) If, on or after 31 August 2019 and before the commencement of subregulations 45(7) to (9):

(a) a person made a request (an ***opioid reform request***) that:

(i) was made in relation to prescription opioids that were registered goods; and

(ii) was made under subsection 9D(2) or (3) of the Act; and

(iii) was made solely for an opioid reform purpose (see subregulation (3)) or solely for an opioid reform purpose and an associated variation of product information purpose (see subregulation (4)); and

(b) the person paid the fee prescribed in Schedule 9 to these Regulations in relation to the request;

the Secretary must, on behalf of the Commonwealth, refund to the person an amount equal to the fee paid.

(3) For the purposes of subregulation (2), an opioid reform request was made for an opioid reform purpose if it was made:

(a) under subsection 9D(2) of the Act, to do either or both of the following:

(i) add a warning, or precaution, in relation to the goods that did not include any comparison of the goods with any other therapeutic goods by reference to quality, safety or efficacy;

(ii) reduce the class of persons for whom the goods were suitable; or

(b) under subsection 9D(3) of the Act, to introduce a smaller pack size in relation to the goods.

(4) For the purposes of subregulation (2), an opioid reform request was made for an associated variation of product information purpose if:

(a) the opioid reform request was made under subsection 9D(3) of the Act; and

(b) paragraphs 9D(3)(b) to (c) of the Act were satisfied in relation to the request; and

(c) the request was made for the purpose of varying product information in relation to the prescription opioids so that the product information would be in the form approved under section 7D of the Act in relation to the prescription opioids.

Subdivision F—Clinical trials

75 Clinical trials

(1) These Regulations have effect as if a written assurance given before 1 January 2020 under paragraph 12AB(2)(a) that clinical trials would be conducted in accordance with the Practice Guidelines were, on and after 1 January 2020, a written assurance that clinical trials would be conducted in accordance with the Practice Guideline.

(2) The amendment of subregulation 12AC(1) made by Part 2 of Schedule 9 to the amending regulations applies in relation to things done on or after 1 January 2020 in relation to a clinical trial that began before, on or after 1 January 2020.

(3) The amendment of paragraph 12AD(a) made by Part 2 of Schedule 9 to the amending regulations applies in relation to uses on or after 1 January 2020 in relation to a clinical trial that began before, on or after 1 January 2020.

(4) The amendment of Schedule 5A made by Part 2 of Schedule 9 to the amending regulations applies in relation to:

(a) requests made on or after 1 January 2020 to give information acquired before, on or after 1 January 2020; and

(b) things mentioned in regulation 12AC done on or after 1 January 2020;

in relation to a clinical trial that began before, on or after 1 January 2020.

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.

Division 14—Application provisions relating to the Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021

78 Exempt goods

(1) Paragraph (a) of item 5 of the table in Schedule 5, as inserted by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, applies in relation to a nicotine vaping product imported on or after the commencement of that item.

(2) Paragraph (b) of item 5 of the table in Schedule 5, as inserted by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, applies in relation to a nicotine vaping product manufactured on or after the commencement of that item.

(3) Paragraph (c) of item 5 of the table in Schedule 5, as inserted by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, applies in relation to a nicotine vaping product supplied on or after the commencement of that item, where that product was imported or manufactured on or after that commencement.

Division 15—Application provisions relating to the Minamata Convention on Mercury (Consequential Amendments) Regulations 2021

79 Application of amendments made by the *Minamata Convention on Mercury (Consequential Amendments) Regulations 2021*

The amendments of these Regulations made by the *Minamata Convention on Mercury (Consequential Amendments) Regulations 2021* apply in relation to the importation into, export from, or manufacture in, Australia of therapeutic goods on or after the commencement of that instrument.

Division 16—Application provisions relating to the Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021

80 Nicotine vaping products

Item 5A of the table in Schedule 5, as inserted by Part 8 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*, applies in relation to kits manufactured on or after the commencement of that Part.

81 Access to medicines in emergency situations

Item 1B of the table in Schedule 5A, as inserted by Part 9 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*, applies in relation to therapeutic goods imported into Australia on or after the commencement of that Part.

82 Consumer medicine information documents

The amendments of regulation 9A (except the amendment of paragraph 9A(1A)(b)) made by Part 10 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* apply in relation to supplies of therapeutic goods on or after the commencement of that Part (whether the goods were included in the Register before, on or after that commencement).

83 Approving supply of therapeutic goods under authorised prescriber scheme

The amendments of regulation 12B made by Part 11 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* apply in relation to an authority given under subsection 19(5) of the Act on or after the commencement of that Part.

Division 17—Application provisions relating to the Therapeutic Goods Legislation Amendment (2021 Measures No. 4) Regulations 2021

84 Amendments made by Division 1 of Part 2 of Schedule 1

(1) The amendment of paragraph 7(g) made by Division 1 of Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 4) Regulations 2021* applies in relation to an advertisement that is made on or after the commencement of that amendment.

(2) The amendment of item 1B of the table in Schedule 5A made by Division 1 of Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 4) Regulations 2021* applies in relation to therapeutic goods imported into Australia on or after the commencement of that amendment.

85 Amendments made by Division 2 of Part 2 of Schedule 1

(1) The amendments of regulation 6B and of Part 1 of Schedule 2 made by Division 2 of Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 4) Regulations 2021* apply in relation to an advertisement that is made on or after the commencement of those amendments.

(2) The amendments of regulation 8 made by Division 2 of Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 4) Regulations 2021* apply in relation to the dissemination of generic information on or after the commencement of those amendments.

Division 18—Application provisions relating to Schedule 1 to the Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022

86 Extemporaneously-compounded medicinal cannabis products

The amendment of Schedule 5 to these Regulations made by Schedule 1 to the *Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022* does not apply in relation to a medicinal cannabis product that is extemporaneously compounded before 28 April 2022.

Division 19—Application provisions relating to Schedule 2 to the Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022

87 Reconsideration of decisions

The amendments of regulation 48 of these Regulations made by Schedule 2 to the *Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022* apply in relation to initial decisions made on or after the commencement of this regulation.

Division 20—Application provisions relating to the Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022

88 Exempt goods

The amendment of item 1 of the table in Schedule 5 made by Schedule 2 to the *Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022* applies in relation to therapeutic goods that are imported on or after the commencement of this regulation.

89 Fee for requests to vary entries in Register

(1) The amendment of item 2A of the table in clause 3 of Schedule 9 made by Schedule 2 to the *Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022* applies in relation to a request that is made on or after the commencement of this regulation.

(2) If:

(a) on or after 1 January 2022 and before the commencement of this regulation, a person made a request of a kind covered by paragraph (c) of item 2A of the table in clause 3 of Schedule 9 (as that item was in force before that commencement); and

(b) on or after 1 January 2022 and before the commencement of this regulation, the person paid the fee applicable in relation to the request under paragraph (c) of that item (as that item was in force before that commencement); and

(c) had the request been made on the day on which this regulation commences, the request would have been covered by paragraph (d) of that item as in force on that commencement;

the Secretary must, on behalf of the Commonwealth, refund to the person the difference between the fee paid and the fee that would have been applicable in relation to the request under paragraph (d) of that item if the request had been made on the day on which this regulation commences.

Division 21—Application provisions relating to the Therapeutic Goods Legislation Amendment (2023 Measures No. 1) Regulations 2023

90 Clinical trials

The amendments of item 3 of the table in Schedule 5A made by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2023 Measures No. 1) Regulations 2023* apply in relation to the use of therapeutic goods on or after the commencement of those amendments, whether the clinical trial began before, on or after that commencement.

Schedule 1—Part 2 does not apply to members of an Australian branch of one of these bodies

(subregulation 4(2))

Column 1 Item No.	Column 2 Body
1	Acupuncture Association of Australia
2	Acupuncture Ethics and Standards Organisation
2A	Association of Natural Health Practitioners Limited
3A	Aust-China Acupuncture and Chinese Medicine Association Inc.
3B	Australasian Federation of Natural Therapists Inc.
4	Australian Acupuncture Association Ltd.
5	Australasian Association of Ayurveda Incorporated
5A	Australian Association of Exercise and Sports Scientists
6	Australian Association of Professional Homoeopaths
6A	Australian College of Acupuncturists Ltd
7	Australian Committee of Natural Therapies Inc. (SA)
9	Australian Federation of Homoeopaths
9A	Australian Federation of Homoeopaths (Qld.) Inc.
9B	Australian Federation of Homoeopaths (WA) Inc.
10	Australian Natural Therapists Association Ltd
11	Australian Naturopathic Practitioners and Chiropractors Association
11A	Australian Society of Homeopaths Inc
12	Australian Traditional Chinese Herbalists Association (Qld)
13	Australian Traditional Chinese Medicine Association Inc.
14	Australian Traditional Medicine Society
14A	Australian Unani Medicines Society Inc.
15	Chinese Medicine Association Pty Ltd
15A	Chinese Medicine Association of Australia Inc.
16	Complementary Medicine Association
16A	Federation of Chinese Medicine and Acupuncture Societies of Australia
17	Homoeopathic Education and Research Association
17A	International Association of Trichologists
17B	International Christian Association of Natural Therapists Ltd (ICANT)
18	National Herbalists Association of Australia
18A	Naturopathic Physicians Association of Australia Inc.
19	Queensland Naturopathic Association
20	Register of Acupuncture and Traditional Chinese Medicine

Column 1 Item No.	Column 2 Body
21	Society of Natural Therapists and Researchers [SNTR] Inc.
22	Society of Classical Homoeopathy Ltd
23	Traditional Medicine of China Society Australia
24	Society of Chinese Medicine and Acupuncture (Vic) Inc.
25	Naturopathic Practitioners Association Inc.
26	The Acupuncture Association of Australia, New Zealand and Asia
26A	The Alumni Association of Natural Medicine Practitioners Inc.
26AA	Australian Society for Bioregulatory Medicine Incorporated
26B	The Australian Podiatry Association (NSW)
26BA	The Homeopathic Medicine Association Inc.
27	The New South Wales Research Association of Traditional Chinese Medicine

Schedule 2—Prohibited and required representations

(regulation 6B)

Part 1—Prohibited representations

Column 1 Item No.	Column 2 Representation	Column 3 Therapeutic goods
3	a representation with respect to the use of goods in which it is stated or implied that those goods: (a) are, or contain, a vitamin—unless those goods are composed of, or contain, a substance specified in column 2 of an item in Part 3 of this Schedule or a salt or derivative of a substance and that substance is described either by the name referred to in Column 2 of that item, or by the name of its salt or derivative, or by the name specified in Column 3 of that item and not otherwise; or (b) are, or contain, a substance described as a vitamin otherwise than by a description specified in Column 2 or 3 of Part 3 of this Schedule	all therapeutic goods
4	a representation that states or implies that: (a) analgesic consumption is safe; or (b) analgesics will relax, relieve tension, sedate or stimulate	analgesics
5	a representation containing a reference to bacteriostatic activity, except where it is made in conjunction with a reference to bactericidal activity	disinfectants
6	a representation: (a) containing reference to the Rideal-Walker test or the Phenol Coefficient; or (b) on any label, containing a reference to the results of laboratory tests on micro-organisms, other than a representation provided by leaflet or on a label enclosed with the goods in their package; or (c) containing a reference to the achievement of sterility except where the representation is approved in writing by the Secretary; or (d) contradicting or conflicting with the common name; or (e) that is not more specific than the common name as a description or measure of activity against micro organisms; or (f) containing a reference to an effect against viruses, except a representation that is approved in writing by the Secretary; or	disinfectants and antiseptics

Column 1 Item No.	Column 2 Representation	Column 3 Therapeutic goods
	(g) containing a reference to an effect against Mycobacterium tuberculosis and related acid fast bacteria, except a representation that is approved in writing by the Secretary; or (h) containing a reference to the disinfection of inaccessible parts of drains	
7	a representation that antiseptics promote healing	antiseptics
8	a representation that states or implies that vitamin or mineral supplements: (a) are a substitute for good nutrition or a balanced diet; or (b) are in any way superior to or more beneficial than dietary nutrients	vitamin or mineral supplements
9	a representation that: (a) purports to show the recommended daily or dietary intake or allowance of a vitamin or a mineral unless the amount shown is that recommended by the National Health and Medical Research Council; or (b) expresses the quantity of a vitamin or a mineral contained in a preparation as a percentage or proportion of the recommended daily or dietary intake or allowance	vitamins and minerals
10	The following: (a) a representation regarding abortifacient action; (b) a representation regarding the treatment, cure, prevention, diagnosis (including screening) or monitoring of, or the susceptibility or pre-disposition to, one or more of the following: (i) neoplastic disease; (ii) sexually transmitted diseases; (iii) human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS); (iv) hepatitis C virus (HCV); (v) mental illness	all therapeutic goods

Part 2—Required representations

Column 1 Item	Column 2 Representation	Column 3 Therapeutic goods
1	if the advertisement is in the form of a label on the retail container—a statement that: (a) vitamins can only be of assistance if the dietary vitamin intake is inadequate; or (b) vitamin supplements should not replace a balanced diet	vitamin preparations for oral ingestion supplied in Australia

Part 3—Vitamins referred to in Item 3 of Part 1 of this Schedule

Column 1 Item	Column 2 Substance	Column 3 Name
1	Vitamin A	—
2	Thiamine	Vitamin B1
3	riboflavin	Vitamin B2
4	Nicotinic Acid	
5	Pantothenic Acid	Vitamin B5
6	Pyridoxine	Vitamin B6
7	Cyanocobalamin	Vitamin B12
8	Ascorbic Acid	Vitamin C
9	Ergocalciferol	Vitamin D2
10	colecalciferol	Vitamin D3
11	alpha-Tocopherol	Vitamin E
12	Biotin	Vitamin H
13	Phytomenadione	Vitamin K1
14	Menadione	Vitamin K3
15	Folic Acid	

Schedule 3—Therapeutic goods required to be included in the part of the Register for goods known as registered goods or as provisionally registered goods

(regulation 10)

Part 1—Medicines

Item No.	Therapeutic goods
1	medicines that: (a) are not mentioned in item 1 of Schedule 4; and (b) are not designated orphan drugs
2	medicines that: (a) are not mentioned in item 3, 4A, 5 or 7 of Schedule 4; and (b) are not designated orphan drugs; and (c) are supplied as pharmaceutical benefits
2A	medicines that: (a) are not mentioned in item 1, 2, 3, 4, 6, 8, 8A, 9 or 11 in Schedule 5; and (b) are not designated orphan drugs; and (c) are supplied as pharmaceutical benefits
2B	medicines that: (a) are not mentioned in item 1, 1A, 3, 4, 5, 7, 8, 9, 10, 11 or 12 in Schedule 5A; and (b) are not designated orphan drugs; and (c) are supplied as pharmaceutical benefits

Part 3—Therapeutic goods attracting no fee under Division 1 or 2 of Part 3-2 of the Act

Item No.	Therapeutic goods
1	Designated orphan drugs

Schedule 4—Therapeutic goods required to be included in the part of the Register for listed goods

(regulation 10)

Item No.	Therapeutic goods
1	therapeutic goods manufactured in Australia for export only other than goods exempt under regulation 12
3	medicines where: (a) the medicine only contains ingredients that are specified in a determination under paragraph 26BB(1)(a) of the Act; and (b) if a determination under paragraph 26BB(1)(b) of the Act specifies requirements in relation to ingredients being contained in the medicine—none of the requirements have been contravened; and (c) the ingredients in the medicine are not of a kind required to be sterile; and (ca) the medicine does not contain a substance included in a Schedule to the Poisons Standard; and (d) the medicine only has indications that are covered by a determination under paragraph 26BF(1)(a) of the Act; and (e) if a determination under paragraph 26BF(1)(b) of the Act specifies requirements in relation to the indications—none of the requirements have been contravened
4A	homoeopathic preparations where: (a) the preparation consists of, or contains a dilution of, mother tincture that is a 1,000 fold dilution, or a lesser dilution, of that mother tincture; and (b) the preparation only contains ingredients that are specified in a determination under paragraph 26BB(1)(a) of the Act; and (c) if a determination under paragraph 26BB(1)(b) of the Act specifies requirements in relation to ingredients being contained in the preparation—none of the requirements have been contravened; and (d) the preparation is not required to be sterile; and (e) the preparation does not contain a substance (other than one that is more than a 1,000-fold dilution of mother tincture) included in a Schedule to the Poisons Standard; and (f) the preparation only has indications that are covered by a determination under paragraph 26BF(1)(a) of the Act; and (g) if a determination under paragraph 26BF(1)(b) of the Act specifies requirements in relation to the indications—none of the requirements have been contravened

Item No.	Therapeutic goods
5	homoeopathic preparations where: (a) each dilution is more dilute than a 1,000 fold dilution of mother tincture; and (b) the preparation only contains ingredients that are specified in a determination under paragraph 26BB(1)(a) of the Act; and (c) if a determination under paragraph 26BB(1)(b) of the Act specifies requirements in relation to ingredients being contained in the preparation—none of the requirements have been contravened; and (d) the preparation is not required to be sterile; and (e) the preparation only has indications that are covered by a determination under paragraph 26BF(1)((a) of the Act; and (f) if a determination under paragraph 26BF(1)(b) of the Act specifies requirements in relation to the indications—none of the requirements have been contravened
7	sunscreen preparations for dermal application, if: (a) the claimed sun protection factor has been established by testing according to the method described in Standard AS/NZS 2604:2012, as in force from time to time; and (b) the performance statements and markings on the label comply with that Standard; and (c) the sunscreen preparation only contains ingredients that are specified in a determination under paragraph 26BB(1)(a) of the Act; and (d) if a determination under paragraph 26BB(1)(b) of the Act specifies requirements in relation to ingredients being contained in the sunscreen preparation—none of the requirements have been contravened; and (e) the sunscreen preparation only has indications that are covered by a determination under paragraph 26BF(1)(a) of the Act; and (f) if a determination under paragraph 26BF(1)(b) of the Act specifies requirements in relation to the indications—none of the requirements have been contravened
8	medicines where: (a) the medicine only contains ingredients that are specified in a determination under paragraph 26BB(1)(a) of the Act; and (b) if a determination under paragraph 26BB(1)(b) of the Act specifies requirements in relation to ingredients being contained in the medicine—none of the requirements have been contravened; and (c) the ingredients in the medicine are not of a kind required to be sterile; and (ca) the medicine does not contain a substance included in a Schedule to the Poisons Standard; and (d) the indications proposed by the sponsor of the medicine are either: (i) uses of the medicine in preventing, curing or alleviating a disease, ailment, defect or injury in persons, other than a form of the disease, ailment, defect or injury that, under the Therapeutic Goods Advertising Code, is a serious form; or (ii) uses of the medicine in connection with alleviating a disease, ailment, defect or injury in persons, being a form of the disease, ailment, defect or injury that, under the Therapeutic Goods Advertising Code, is a serious form; and (e) the indications proposed by the sponsor of the medicine do not refer to an indication that is or contains a prohibited representation (within the meaning of Part 5-1 of the Act
12	kits (to be known as ***medicine kits***) consisting as follows:

Item No.	Therapeutic goods
	(a) solely of medicines—if Part 3-2 of the Act applies to any of the individual therapeutic goods contained in the kit; (b) of medicines and biologicals—if: (i) Part 3-2 of the Act applies to any of the individual therapeutic goods (other than biologicals) contained in the kit; and (ii) Part 3-2A of the Act applies to any of the biologicals contained in the kit
16	hospital grade disinfectants, or household grade disinfectants, that are claimed to be sterilants, fungicides, sporicides, tuberculocides or virucides

Schedule 5—Therapeutic goods exempt from the operation of Parts 3-2 and 3-2A of the Act

(subregulation 12(1))

Column 1 Item No.	Column 2 Therapeutic goods
1	therapeutic goods that are imported for use in the treatment of the importer or the importer's immediate family where: (a) the goods do not contain a substance the importation of which is prohibited under the *Customs Act 1901*; and (ba) for a biological—the biological is the subject of an approval under section 32CK of the Act; and (c) in the case of other medicines: (i) the quantity imported in one importation is not more than 3 months' supply at the maximum dose recommended by the manufacturer; and (ii) the total quantity of the medicine imported for use in the treatment of the importer or the importer's immediate family in the period of 12 months ending on the day on which the latest importation occurs does not exceed 15 months' supply of the medicine at the maximum dose recommended by the manufacturer; or the medicines have been approved, or are included in a class of medicines that has been approved, under regulation 5 of the Customs (Prohibited Imports) Regulations for importation into Australia; and (d) if the goods are subject to Schedule 4 or Schedule 8 to the Poisons Standard—the goods are the subject of a written authority issued by a medical practitioner registered under a law of a State or Territory, except where the goods are carried by the importer as a passenger on a ship or aeroplane
2	therapeutic goods that are exported and that: (a) are not for commercial supply; and (b) do not contain a substance the exportation of which is prohibited under the *Customs Act 1901*; and (c) are not intended for use in clinical trials on humans
3	samples of therapeutic goods imported, exported, manufactured, or supplied for: (a) submission to a regulatory authority; or (b) subjection to developmental or quality control procedures; or (c) examination, demonstration or display; or (d) subjection to analysis or laboratory testing procedures; but not for supply for therapeutic use in humans
4	goods imported solely for the purpose of export that remain subject to customs control under the *Customs Act 1901* and that are not subject to manufacture in Australia
5	The following goods: (a) a nicotine vaping product where: (i) that product is imported; and

Column 1 Item No.	Column 2 Therapeutic goods
	(ii) the sponsor reasonably expects that product to be supplied to the ultimate consumer of the product in accordance with an approval under subsection 19(1) of the Act or an authority under subsection 19(5) of the Act; (b) a nicotine vaping product where: (i) that product is manufactured by the holder of a licence; and (ii) the manufacturer reasonably expects that product to be supplied to the ultimate consumer of the product in accordance with an approval under subsection 19(1) of the Act or an authority under subsection 19(5) of the Act; (c) a nicotine vaping product where: (i) that product is supplied in Australia by a person (the ***intermediate supplier***) to a person who is not the ultimate consumer of the product; and (ii) the intermediate supplier reasonably expects that product to be supplied to the ultimate consumer of the product in accordance with an approval under subsection 19(1) of the Act or an authority under subsection 19(5) of the Act.
5A	a kit covered by subsection 7B(1) of the Act if: (a) the kit contains one or more nicotine vaping products; and (b) the kit does not contain any other therapeutic goods
6	medicines that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person, other than medicines that are used for gene therapy or that are medicinal cannabis products
6A	medicines (other than medicines that are used for gene therapy or that are medicinal cannabis products) that are: (a) compounded in a hospital by: (i) in the case of a private hospital—a hospital pharmacist who is engaged in the manufacture of therapeutic goods (other than biologicals) on the premises of the private hospital; or (ii) in the case of a public hospital—a pharmacist who is employed by the public hospital and is engaged in the manufacture of therapeutic goods (other than biologicals); and (b) compounded in anticipation of being needed for therapeutic application to patients of the hospital; and (c) considered by the hospital's drug and therapeutic committee (however called) to be appropriate for compounding in anticipation of being needed to treat a patient at the hospital
7	manufacturing, laboratory and dispensary equipment used in the preparation of therapeutic goods
8	the following goods, unless the goods are for the treatment, cure, prevention, diagnosis or monitoring of, or testing susceptibility of persons to, a disease, condition, ailment or defect: (a) homoeopathic preparations more dilute than a one thousand fold dilution of a mother tincture and which are not required to be sterile; and which do not include an ingredient of: (i) human origin; or (ii) animal origin, if the ingredient consists of, or is derived from, any of the following parts of cattle, sheep, goats or mule deer: (A) adrenal;

Column 1 Item No.	Column 2 Therapeutic goods
	(B) brain; (C) cerebrospinal fluid; (D) dura mater; (E) eye; (F) ileum; (G) lymph nodes; (H) pineal gland; (I) pituitary; (J) placenta; (K) proximal colon; (L) spinal cord; (M) spleen; (N) tonsil; (c) unmedicated anti-acne preparations having only a cleansing action or purpose; (d) medicated insect repellents for dermal use if the medication consists solely of an antiseptic having a secondary role in the formulation, except those that are included in a Schedule to the Poisons Standard; (f) disinfectants, except those described in item 16 in Schedule 4; (g) sunscreen preparations for dermal application, if: (i) the claimed sun protection factor has been established by testing according to the method described in Standard AS/NZS 2604:2012, as in force from time to time; and (ii) the performance statements and markings on the label comply with that Standard; and (iii) the sun protection factor stated on the label is less than 4, unless the preparations include ingredients of human origin, or of animal origin if the ingredient consists of, or is derived from, any of the following parts of cattle, sheep, goats or mule deer: (A) adrenal; (B) brain; (C) cerebrospinal fluid; (D) dura mater; (E) eye; (F) ileum; (G) lymph nodes; (H) pineal gland; (I) pituitary; (J) placenta; (K) proximal colon; (L) spinal cord; (M) spleen; (N) tonsil
8A	Lotions, shampoos or hairdressings for the prevention or treatment of dandruff, except those that: (a) are included in a Schedule to the Poisons Standard; or (b) are also for the treatment, cure, prevention, diagnosis or monitoring of, or testing susceptibility of persons to, another disease, condition, ailment or defect

Column 1 Item No.	Column 2 Therapeutic goods
8B	unmedicated preparations for topical use for protecting against, or providing relief from, nappy rash symptoms by acting only as a barrier for the skin (whether or not the preparations also have a moisturising action)
9	Starting materials that are ingredients or components for use in the manufacture of therapeutic goods, except when: (a) prepackaged for supply for other therapeutic purposes; or (b) formulated as a dosage form
10	medicines that are blood and blood components manufactured by the holder of a licence to manufacture blood and blood components
11	therapeutic goods: (a) in relation to the importation of which a permission, licence or declaration under regulation 5A, 5B or 5C of the Customs (Prohibited Imports) Regulations granted or made before the commencement of the Act is in force; and (b) which are supplied in Australia for use in humans not more than 6 months after the commencement of the Act
12	allergens for skin patch testing on unbroken skin, whether or not the allergen is also described in an item in Schedule 3 or 4
13	radiopharmaceutical cold kits that are: (a) containers of sterile reagents to which radioisotope is added immediately before injection into patients; and (b) manufactured by a radiochemist or a pharmacist in a public or private hospital for subsequent extemporaneous compounding and dispensing for use by, or in connection with: (i) a patient of that hospital; or (ii) a patient of another public or private hospital in the same State or Territory
14	(a) tampons; and (b) menstrual cups

Schedule 5A—Therapeutic goods exempt from operation of Parts 3-2 and 3-2A of Act subject to conditions

(subregulations 12(2) and (3))

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
1	Therapeutic goods imported into Australia that are held under the direct control of the sponsor, until the goods are: (a) the subject of a notification under item 3; or (b) approved for importation into Australia under subsection 19(1), section 19A, subsection 32CK(1) or section 32CO of the Act; or (c) authorised for supply under subsection 19(5) or 32CM(1) of the Act; or (ca) authorised for supply under rules made under subsection 19(7A) or 32CM(7A) of the Act; or (d) dispensed as a medicine or biological prescribed for a Category A patient within the meaning of subregulation 12A(5); or (e) exported from Australia	(a) the supply of the goods must be in accordance with the relevant notification, approval, authorisation or prescription; and (b) the goods must be kept in a warehouse or a properly secured area under the control of the sponsor; and (d) the sponsor must: (i) keep records relating to the source and supply of the goods; and (iii) if requested by the Secretary, give the records to the Secretary
1A	Therapeutic goods imported into Australia and held under the direct control of the sponsor, until a decision is made under section 25, 26, 26A, 26AE, 32DB, 32DC, 32DF or 32DG of the Act about the goods	(a) the sponsor must: (i) keep records about the source of the goods; and (ii) if requested by the Secretary, give the records to the Secretary; and (iii) have lodged an application under section 23, 32DA or 32DD of the Act for the goods before their importation; and (b) if the goods are not registered, listed, or included in the Register under Part 3-2A of the Act: (i) in the case of therapeutic goods other than

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
		biologicals—the goods must be destroyed; or (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
1B	Therapeutic goods imported into Australia that are needed for dispensing as a medicine prescribed for persons who are seriously ill with a condition from which premature death is reasonably likely to occur in the absence of early treatment	(a) the goods must be supplied to a person covered by column 2 in circumstances where subparagraphs 12A(2)(a)(ii) and (iii) and paragraph 12A(2)(b) of these Regulations are satisfied; and (b) until the goods need to be so supplied, either or both of the following apply: (i) the goods are kept in a warehouse or a properly secured area under the control of the sponsor; (ii) the goods are kept at a hospital or other healthcare facility after being delivered to the hospital or facility by, or on behalf of, the sponsor; and (c) the sponsor must: (i) keep records relating to the source, and delivery, of the goods; and (ii) if requested by the Secretary, give the records to the Secretary
2	Therapeutic goods that are medicinal cannabis products manufactured in Australia under a licence granted under Part 3-3 of the Act and are held under the direct control of the sponsor, until the goods are: (a) the subject of a notification under item 3; or (b) approved for supply in Australia under subsection 19(1) or section 19A of the Act; or (c) authorised for supply under subsection 19(5) of the Act; or (d) authorised for supply under rules made under subsection 19(7A) of the Act	(a) the supply of the goods must be in accordance with the relevant notification, approval or authorisation; and (b) the goods must be kept in a warehouse or a properly secured area under the control of the sponsor; and (c) the sponsor must: (i) keep records relating to the source and supply of the goods; and (ii) if requested by the Secretary, give the records to the Secretary
2A	Therapeutic goods that are medicinal cannabis products	the sponsor must:

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
	manufactured in Australia under a licence granted under Part 3-3 of the Act and are held under the direct control of the sponsor, until a decision is made under section 25 or 26 of the Act about the goods	(a) keep records about the source of the goods; and (b) if requested by the Secretary, give the records to the Secretary; and (c) have lodged an application under section 23 of the Act for the goods before their manufacture
3	Therapeutic goods to be used in a clinical trial solely for experimental purposes in humans	(a) the sponsor must notify the Secretary: (i) in a form approved by the Secretary; and (ii) in accordance with the requirements (if any) determined by the Secretary for the form of notification; about the trial and the therapeutic goods covered by the trial and must do so before: (iii) the goods begin to be used in the trial, unless subparagraph (iv) applies; or (iv) if the sponsor seeks the Secretary's agreement to the notification being given before the end of a period nominated by the sponsor and the Secretary agrees to this—the end of that nominated period; and that the sponsor intends to sponsor a clinical trial using specified goods; and (b) the notification referred to in paragraph (a) must be accompanied by the relevant notification fee referred to in paragraph (a) of column 2 of item 14 in the table in clause 3 of Schedule 9 or paragraph (a) of the column headed "Matter" in item 17 of the table in Part 2 of Schedule 9A; and (c) the approval of the goods for this purpose must be given by the sponsor (if the sponsor is conducting the trial), or by the body or organisation conducting the trial for the sponsor, having regard to the advice of the ethics committee that has, or will assume, responsibility for monitoring the conduct of the trial; and (d) the terms of the approval by the sponsor, body or organisation referred to in paragraph (c) must be no less restrictive than the terms advised by the ethics committee; and (e) the Secretary must not, at any time: (i) have become aware that to conduct or continue the trial would be contrary to the public interest; and (ii) have directed that the trial not be conducted, or be stopped; and (f) the sponsor (if the sponsor is conducting the trial), or

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
		the body or organisation conducting the trial for the sponsor, must not receive, or have received, advice from the ethics committee that is inconsistent with the continuation of the trial; and (g) the conditions set out in regulation 12AD must be complied with, as if that regulation applied to a person using therapeutic goods under this item; and (h) the goods are not any of the following: (i) a Class 4 biological that has not received clinical trial approval for an equivalent indication from a national regulatory agency with comparable regulatory requirements; (ii) a Class 4 biological that does not have a history of previous usage that is supported by clinical evidence received by the TGA; and (ha) the sponsor must notify the Secretary: (i) in a form approved by the Secretary; and (ii) in accordance with the requirements (if any) determined by the Secretary for the form of notification; about any trial site not covered by the notification referred to in paragraph (a) and must do so before: (iii) the goods begin to be used at that site, unless subparagraph (iv) applies; or (iv) if the sponsor seeks the Secretary's agreement to the notification being given before the end of a period nominated by the sponsor and the Secretary agrees to this—the end of that nominated period; and (hb) the notification referred to in paragraph (ha) must be accompanied by the relevant notification fee referred to in paragraph (b) of column 2 of item 14 in the table in clause 3 of Schedule 9 or paragraph (b) of the column headed "Matter" in item 17 of the table in Part 2 of Schedule 9A; and (i) the sponsor must comply with requests by an authorised officer, whether made before or after the start of the trial, to give information about the conduct of the trial (whether or not the sponsor is conducting the trial); and (j) if a body or organisation is conducting the trial for the sponsor, that body or organisation must comply with requests by an authorised officer, whether made before or after the start of the trial, to give information about the conduct of the trial; and (k) the sponsor (if the sponsor is conducting the trial), or the body or organisation conducting the trial for the sponsor, must allow an authorised officer to do

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
		the things mentioned in regulation 12AC
4	Therapeutic goods that are imported by a member of a group of persons	(a) the group must be visiting Australia to participate in a national or an international sporting event; and (b) the goods must be for use in the treatment of a member or members of that group; and (c) the importation of the goods must not be prohibited under the Customs (Prohibited Imports) Regulations; and (d) the goods must not be supplied to, or used in the treatment of, a person who is not a member of the visiting group; and (e) any portion of the goods that is unused at the end of the visit must be destroyed or removed from Australia; and (f) a member of the group must be responsible for the control and custody of the goods while the group is in Australia; and (g) the person referred to in paragraph (f) must: (i) carry a list, in English, of the quantity and nature of the therapeutic goods imported; and (ii) for each of the goods that is not a biological—include in the list the generic name and strength of the active ingredient of the goods; and (iii) keep a record of the use of the goods while the group is in Australia; and (iv) produce the list or the record for inspection at the request of a customs officer or a person who is an authorised officer for the purposes of a provision of Part 5 of these Regulations
5	Therapeutic goods, if: (a) the goods are not: (i) biologicals; or (ii) goods referred to in item 3; and (b) the goods are manufactured by a person under a contract between the person and a private hospital, a public hospital in a State or Territory or a public institution (the ***relevant institution***); and (c) the manufacture is in accordance with a formulation specified by the relevant institution; and	(a) there are no listed goods or registered goods that, in all relevant respects, are substantially similar to the goods; and (b) the person: (i) manufactures the goods at premises in Australia; and (ii) holds a licence, required by the Act, that authorises the manufacture, or a step in the manufacture, of the goods at those premises; and (c) the person notifies the Secretary, in accordance with a form approved by the Secretary and within 15 days of the end of a quarter, of: (i) the goods manufactured under the contract during that quarter; and (ii) the relevant institution that entered the contract

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
	(d) the goods are for use by, or in connection with, a patient of: (i) the relevant institution; or (ii) if the relevant institution is a public hospital in a State or Territory—another public hospital in the State or Territory	
7	Therapeutic goods, or parts of therapeutic goods, that form part of a medicine delivery system in which the medicine is supplied in a device that acts as a container	(a) none of the goods, or any part of the goods are separately supplied in Australia; and (b) if the component and kit manufacturer are the same manufacturer and the components are not separately supplied outside the kit by the kit sponsor; and (c) if the kit sponsor or the manufacturer obtains components from other manufacturers and the kit manufacturer's licence covers quality control of those components
8	Therapeutic goods imported by a member of a group of persons	(a) the group must be members of the military forces of another country, visiting Australia for military training; and (b) the goods must be for use in the treatment of a member or members of that group; and (c) the goods must not be supplied to, or used in the treatment of, a person other than a member of: (i) the visiting group; or (ii) the Australian Defence Force; and (d) any portion of the goods that is unused at the end of the visit must be destroyed or removed from Australia; and (e) a member of the group to whom the goods have been issued must be responsible for the control and custody of the goods while the group is in Australia; and (f) the person mentioned in paragraph (e) must: (i) carry a list, in English, of the quantity and nature of the therapeutic goods imported; and (ii) for each of the goods that is not a biological—include in the list the generic name and strength of the active ingredient of the goods; and (iii) keep a record of the use of the goods while the group is in Australia; and (iv) produce the list or the record for inspection at the request of a customs officer or a person

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
		who is an authorised officer for a provision of Part 5 of these Regulations
9	Unused emergency goods or unused emergency biologicals directed by the Secretary, under clause 7 of Schedule 5B, to be exported	the provisions of Schedule 5B continue to apply to the goods or biologicals, as if the goods or biologicals were not exempt from the operation of section 30G or 32CG of the Act
10	Therapeutic goods imported into Australia by a medical practitioner or a member of a medical team (being 1 or more persons under the professional supervision of a medical practitioner)	(a) the medical practitioner or medical team must be accompanying a person to Australia who: (i) has a critical illness; and (ii) is under the direct care and supervision of the practitioner or team; and (b) the goods must be for use in the treatment of the person who has the critical illness; and (c) the importation of the goods must not be prohibited under the *Customs (Prohibited Imports) Regulations 1956*; and (d) the quantity of the goods must be consistent with the quantity required for the treatment of the person mentioned in paragraph (b); and (e) the goods must not be supplied to, or used in the treatment of, a person other than the person mentioned in paragraph (b); and (f) any portion of the goods that is unused at the end of the visit must be destroyed or removed from Australia; and (g) the medical practitioner, or a member of the medical team, must be responsible for the control and custody of the goods while the practitioner or team is in Australia; and (h) the person mentioned in paragraph (g) must: (i) carry a list, in English, of the quantity and nature of the therapeutic goods imported; and (ii) for each of the goods that is not a biological—include in the list the generic name and strength of the active ingredient of the goods; and (iii) keep a record of the use of the goods while the medical practitioner or medical team is in Australia; and (iv) produce the list or record for inspection at the request of a customs officer or a person who is an authorised officer for the purposes of a provision of Part 5 of these Regulations.
11	Therapeutic goods imported into Australia by a member of a group of persons	(a) the group must include a person who is the Head of State or Head of Government of a foreign country and senior Government officials of that country,

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
		who are visiting Australia on official business; and (b) the goods must be for use in the treatment of a member or members of the visiting group; and (c) the importation of the goods must not be prohibited under the *Customs (Prohibited Imports) Regulations 1956*; and (d) the goods must not be supplied to, or used in the treatment of, a person other than a member of the visiting group; and (e) any portion of the goods that is unused at the end of the visit must be destroyed or removed from Australia; and (f) a member of the visiting group must be responsible for the control and custody of the goods while the group is in Australia; and (g) the person mentioned in paragraph (f) must: (i) carry a list, in English, of the quantity and nature of the therapeutic goods imported; and (ii) for each of the goods that is not a biological—include in the list the generic name and strength of the active ingredient of the goods; and (iii) keep a record of the use of the goods while the group is in Australia; and (iv) produce the list or record for inspection at the request of a customs officer or a person who is an authorised officer for the purposes of a provision of Part 5 of these Regulations.
12	Therapeutic goods that are part of the medical supplies of a ship (including a yacht or other marine vessel) or aircraft visiting Australia	(a) the goods must be for use in the treatment of a passenger or a member of the crew travelling on the ship or aircraft; and (b) the importation of the goods must not be prohibited under the *Customs (Prohibited Imports) Regulations 1956*; and (c) the quantity of the goods must be consistent with the quantity required for the treatment of passengers and members of the crew travelling on the ship or aircraft; and (d) the goods must not be supplied to, or used in the treatment of, a person other than a passenger or a member of the crew travelling on the ship or aircraft; and (e) the goods must not be removed from the ship or aircraft while the ship or aircraft is in Australia; and (f) the master of the ship or the pilot of the aircraft must be responsible for the control and custody of the goods while the ship or aircraft is in Australia; and

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
		(g) the person mentioned in paragraph (f) must: (i) carry a list, in English, of the quantity and nature of the therapeutic goods imported; and (ii) for each of the goods that is not a biological—include in the list the generic name and strength of the active ingredient of the goods; and (iii) keep a record of the use of the goods while the ship or aircraft is in Australia; and (iv) produce the list or record for inspection at the request of a customs officer or a person who is an authorised officer for the purposes of a provision of Part 5 of these Regulations.
13	Therapeutic goods in relation to which all of the following paragraphs apply: (a) the goods comprise, contain or are derived from human cells or human tissues collected from a patient who is under the clinical care of a medical or dental practitioner; (b) the goods were manufactured by, or under the professional supervision of, the practitioner; (c) the single indication of the goods is homologous use: (i) on that patient; and (ii) in a single clinical procedure; and (iii) by, or under the professional supervision of, that practitioner; (d) the goods have been subjected to only minimal manipulation; (e) the practitioner is registered in a State or internal Territory	if the sponsor knows that particular information relating to an event or occurrence indicates that use of the goods as intended by the sponsor may have an unintended harmful effect, the sponsor must give the information to the Secretary within the period specified by regulation 16AB
14	Therapeutic goods in packs, if: (a) the packs contain tampons or menstrual cups; and	the packs must not be supplied: (a) by persons other than charities; or (b) for a charge; or

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
	(b) any other therapeutic goods in the packs are included in the Register; and (c) the packaging of any individually packaged medical devices or medicines in the pack is intact; and (d) the packs do not contain any of the following: (i) a biological; (ii) a medicine mentioned in Part 1 of Schedule 10; (iii) a medical device (other than an IVD medical device) that is classified under the *Therapeutic Goods (Medical Devices) Regulations 2002* as Class IIa or higher; (iv) an IVD medical device or in-house IVD medical device that is classified under the *Therapeutic Goods (Medical Devices) Regulations 2002* as Class 2 or higher	(c) to persons other than homeless or disadvantaged women

Schedule 5B—Disposal of unused emergency goods and unused emergency biologicals

(regulation 12AAB)

1 Early end of exemption—notice of goods held

(1) This clause applies if:

(a) the Minister makes an exemption under subsection 18A(1) of the Act in relation to specified therapeutic goods or therapeutic goods in a specified class; and

(b) a person is given a copy of a revocation or variation of the exemption under paragraph 18A(9B)(b) of the Act.

(2) The person must give the Secretary:

(a) notice, in writing, of the quantity and location of:

(i) for a revocation—the goods over which the person has control that have not been used; or

(ii) for a variation—the goods mentioned in the variation over which the person has control that have not been used; and

(b) a copy of any records about the goods that the person is required to keep under a condition of the exemption.

(3) The person must comply with subclause (2) in relation to the goods within 7 days after the day the exemption ends for the goods.

1A Early cessation of exemption—notice of biologicals held

(1) A person who is given notice under paragraph 32CE(b) of the Act must give to the Secretary:

(a) notice, in writing, of the quantity and location of any unused emergency biologicals over which the person has control; and

(b) a copy of any records about the biologicals that, under a condition of the exemption, the person is required to keep.

(2) Subclause (1) must be complied with:

(a) if the notice under paragraph 32CE(b) of the Act is given before the exemption ceases to have effect for the biologicals—within 7 days after the exemption ceases; or

(b) in any other case—within 7 days after the notice is given.

2 Expiration of period of exemption—notice of goods held

A person who has been importing, manufacturing, supplying or exporting therapeutic goods under an exemption under subsection 18A(1) of the Act must, within 7 days after the exemption ceases to have effect under paragraph 18A(4)(a) of the Act, give to the Secretary:

(a) notice, in writing, of the quantity and location of any unused emergency goods over which the person has control; and

(b) a copy of any records about the goods that, under a condition of the exemption, the person is required to keep.

2A Expiration of period of exemption—notice of biologicals held

A person who has been importing, manufacturing, supplying or exporting biologicals under an exemption under subsection 32CB(1) of the Act must, within 7 days after the end of the period specified in the exemption under subsection 32CB(4), give to the Secretary:

(a) notice, in writing, of the quantity and location of any unused emergency biologicals over which the person has control; and

(b) a copy of any records about the biologicals that, under a condition of the exemption, the person is required to keep.

3 Storage and disposal of unused emergency goods and unused emergency biologicals

(1) A person who has control over unused emergency goods or unused emergency biologicals must ensure that those unused emergency goods or unused emergency biologicals are stored in a way that ensures that:

(a) the goods or biologicals are only accessible for supply, export, use or disposal in accordance with the Act and these Regulations; and

(b) the security of the goods or biologicals is appropriate to the level of risk that the goods or biologicals could pose to the public and the environment; and

(c) the integrity of the condition of the goods or biologicals is maintained.

(2) A person may dispose of unused emergency goods or unused emergency biologicals only in accordance with a direction given by the Secretary under subclause 4(1).

4 Direction for disposal of unused emergency goods and unused emergency biologicals

(1) The Secretary may direct, in writing, any person who has control over unused emergency goods or unused emergency biologicals to dispose of the unused emergency goods or unused emergency biologicals in the manner directed.

(2) A direction given under subclause (1) must be in accordance with clause 5, 6, 7 or 8.

(3) A person who has been given a direction under subclause (1) must comply with the direction.

5 Relocation of unused emergency goods and unused emergency biologicals

If storage of particular unused emergency goods or unused emergency biologicals at a particular location poses, or would pose, a risk to the public or the environment, the Secretary may direct that the goods or biologicals be stored at a specified location that will ensure compliance with subclause 3(1).

6 Disposal of unused emergency goods and unused emergency biologicals—destruction

(1) The Secretary may direct that unused emergency goods or unused emergency biologicals be destroyed within the time specified in the direction if any of the following applies:

(a) the goods or biologicals have passed their expiry date;

(b) the goods or biologicals no longer conform to a standard that applies to the goods or biologicals;

(c) use of the goods or biologicals poses, or would pose, a risk to public health;

(d) storage of the goods or biologicals at their current location and any other location poses, or would pose, a risk to the public or the environment;

(e) for unused emergency goods—within 12 months after the exemption ceases to have effect in relation to the goods, the goods have not become (whether in relation to an indication for which the goods could have been used under the exemption or in relation to a different indication):

(i) registered goods or listed goods; or

(ii) exempt goods under section 18 of the Act; or

(iii) goods that are the subject of an approval or authority under section 19 of the Act; or

(iv) goods that are the subject of an approval under section 19A of the Act;

(ea) for unused emergency biologicals—within 12 months after the exemption ceases to have effect in relation to the biologicals, the biologicals have not become (whether in relation to an indication for which the biologicals could have been used under the exemption or in relation to a different indication):

(i) included in the Register under Part 3-2A of the Act; or

(ii) exempt biologicals under section 32CA of the Act; or

(iii) biologicals that are the subject of an approval or authority under section 32CK or 32CM of the Act; or

(iv) biologicals that are the subject of an approval under section 32CO of the Act;

(f) the person who has control over the goods or biologicals requests that the goods or biologicals be destroyed.

(2) A person directed to destroy the goods or biologicals may destroy the goods or biologicals only in a way, approved by the Secretary, that ensures that the destruction avoids or minimises harm to the public and the environment.

7 Disposal of unused emergency goods and unused emergency biologicals—export

(1) This clause applies to unused emergency goods or unused emergency biologicals to which any of paragraphs 6(1)(a) to (e) applies.

(2) The Secretary may direct that the goods or biologicals be exported to a country, instead of directing that they be destroyed, if a relevant authority of the country has confirmed, in writing or by electronic communication, its willingness to accept the goods or biologicals.

(3) A person directed to export the goods or biologicals must ensure that, during exportation:

(a) the goods or biologicals are only accessible for purposes relating to the export; and

(b) the security of the goods or biologicals is appropriate to the level of risk that the goods or biologicals could pose to the public and the environment; and

(c) the integrity of the condition of the goods or biologicals is maintained.

(4) In this clause:

electronic communication has the meaning given by subsection 5(1) of the *Electronic Transactions Act 1999*.

8 Disposal of unused emergency goods and unused emergency biologicals—supply

(1) This clause applies to unused emergency goods or unused emergency biologicals that have become (whether in relation to an indication for which the unused emergency goods or unused emergency biologicals could have been used under the exemption or in relation to a different indication):

(a) registered goods or listed goods; or

(aa) biologicals included in the Register under Part 3-2A of the Act; or

(b) goods that are the subject of an approval or authority under section 19 of the Act; or

(ba) biologicals that are the subject of an approval or authority under section 32CK or 32CM of the Act; or

(c) goods that are the subject of an approval under section 19A of the Act; or

(d) biologicals that are the subject of an approval under section 32CO of the Act.

(2) The Secretary may direct that the goods or biologicals be supplied to an authorised person (otherwise than by way of administration to, or application in the treatment of, the person).

(3) In this clause:

authorised person means, as appropriate, a person:

(a) in relation to whom the registered goods or listed goods are registered or listed; or

(aa) in relation to whom the biologicals are included in the Register under Part 3-2A of the Act; or

(b) to whom the approval under subsection 19(1) or section 32CK of the Act, or the authority under subsection 19(5) or 32CM(1) of the Act, is given; or

(ba) who is included in a class of health practitioners specified in rules made under subsection 19(7A) or 32CM(7A) of the Act; or

(c) to whom the approval under section 19A or 32CO of the Act is given.

9 Owner to be paid for goods or biologicals supplied

A direction given under clause 7 or 8 does not affect a person's liability to pay the owner of the goods or biologicals for the export or supply of the goods or biologicals to the person.

10 Records about unused emergency goods and unused emergency biologicals

A person who has, or has had, control over unused emergency goods or unused emergency biologicals must:

(a) ensure that records are kept that include the following information:

(i) the quantities of the goods or biologicals under the person's control;

(ii) how the goods or biologicals are stored before being disposed of;

(iii) if a direction under subclause 4(1) has been received—what actions have been taken to dispose of the goods or biologicals as directed and when the actions were taken;

(iv) if the goods or biologicals have been exported or supplied—to whom they were exported or supplied and in what quantity; and

(b) retain the records for 7 years after the last entry is made; and

(c) if the Secretary so requests in writing—give to the Secretary a copy of a record mentioned in paragraph (a):

(i) within 14 days after being notified of the Secretary's request; or

(ii) if the information is required to establish whether the goods or biologicals pose imminent risk to the public or the environment—within 24 hours, or any shorter period, specified by the Secretary.

11 Failure to comply with this Schedule

If a person who has control over any unused emergency goods or unused emergency biologicals has not complied with a provision of this Schedule, the Secretary may direct, in writing, that the unused emergency goods or unused emergency biologicals be destroyed by another person.

Schedule 7—Therapeutic goods exempt from the operation of Part 3-3 of the Act unless supplied as pharmaceutical benefits

(regulation 17)

Column 1 Item No.	Column 2 Therapeutic goods
1	goods prepared for the initial experimental studies in human volunteers
2	ingredients, except water, used in the manufacture of therapeutic goods where the ingredients: (a) do not have a therapeutic action; or (b) are herbs, bulk hamamelis water or oils extracted from herbs, the sole therapeutic use of which is as starting materials for use by a licensed manufacturer
6	dentifrices that contain no therapeutically active substance other than not more than 1000 milligrams per kilogram of fluoride
7	homoeopathic preparations more dilute than a one thousand fold dilution of a mother tincture and that are not required to be sterile
8	antiperspirant preparations that derive their antiperspirant properties from inorganic salts of aluminium, zinc or zirconium only
9	unmedicated anti-acne preparations having only a cleansing action or purpose
10	medicated insect repellents for dermal use, if the medication consists solely of an antiseptic having a secondary role in the formulation
11	lotions, shampoos or hairdressings for the prevention or treatment of dandruff
11A	unmedicated preparations for topical use for protecting against, or providing relief from, nappy rash symptoms by acting only as a barrier for the skin (whether or not the preparations also have a moisturising action)
12	medicated soaps other than liquid medicated soaps
13	disinfectants
14	sunscreen preparations for dermal use that: (a) are packaged in containers the labels of which include a statement that the preparations have a sun protection factor below 4 or the equivalent category description; and (b) when tested as described in Standard AS/NZS 2604:2012, as in force from time to time, are established to have a sun protection factor below 4 or the equivalent category description
15	medicated throat lozenges, where the medication consists only of volatile oils and their constituents either alone or in combination with ascorbic acid or its salts
16	medicated space sprays where the medication consists only of volatile oils and their constituents
17	bulk, liquified medical gases

Column 1 Item No.	Column 2 Therapeutic goods
18	blood and blood components that are: (a) collected by a medical practitioner, registered under a law of a State or Territory, or a person under the professional supervision of such a practitioner, in the course of medical treatment and for the purposes of diagnosis of, and testing for, a medical condition; or (b) manufactured by a medical practitioner, registered under a law of a State or Territory, or a person under the professional supervision of such a practitioner, for therapeutic application to a patient under the practitioner's care; or (c) manufactured by a blood donation centre for a medical practitioner, registered under a law of a State or Territory, for therapeutic application to a particular patient under the practitioner's care
19	allergens for skin patch testing on unbroken skin
20	Medicinal oxygen cylinders that have been decant filled, transfilled or cascade filled by: (a) a hospital; or (b) an ambulance, fire or rescue service
21	Therapeutic goods in relation to which all of the following paragraphs apply: (a) the goods comprise, contain or are derived from human cells or human tissues collected from a patient who is under the clinical care of a medical or dental practitioner; (b) the goods are manufactured by, or under the professional supervision of, the practitioner; (c) the single indication of the goods is homologous use: (i) on that patient; and (ii) in a single clinical procedure; and (iii) by, or under the professional supervision of, that practitioner; (d) the goods have been subjected to only minimal manipulation; (e) the practitioner is registered in a State or internal Territory
22	radiopharmaceuticals that are: (a) manufactured by: (i) a medical practitioner registered under a law of a State or Territory when employed by a public or private hospital or a public institution, or a person under the professional supervision of such a medical practitioner; or (ii) a radiochemist when employed by a public or private hospital or a public institution, or a person under the professional supervision of such a radiochemist; or (iii) a pharmacist registered under a law of a State or Territory when employed by a public or private hospital or a public institution, or a person under the professional supervision of such a pharmacist; and (b) for supply to another public or private hospital, another public institution or a private institution within Australia for the purposes of: (i) diagnosing a medical condition in respect of a patient of the hospital or institution; or (ii) treating a medical condition of a patient of the hospital or institution

Column 1 Item No.	Column 2 Therapeutic goods
23	radiopharmaceutical active ingredients that are: (a) manufactured by: (i) a medical practitioner registered under a law of a State or Territory when employed by a public or private hospital or a public institution, or a person under the professional supervision of such a medical practitioner; or (ii) a radiochemist when employed by a public or private hospital or a public institution, or a person under the professional supervision of such a radiochemist; or (iii) a pharmacist registered under a law of a State or Territory when employed by a public or private hospital or a public institution, or a person under the professional supervision of such a pharmacist; and (b) for supply to another public or private hospital, another public institution or a private institution within Australia, which are then used by the hospital or institution to manufacture a radiopharmaceutical for the purposes of: (i) diagnosing a medical condition in respect of a patient of the hospital or institution; or (ii) treating a medical condition of a patient of the hospital or institution

Schedule 8—Persons exempt from the operation of Part 3-3 of the Act

(regulation 18)

Column 1 Item	Column 2 Persons	Column 3 Matter in relation to which person exempted
1	medical practitioners, dentists and other health care workers registered under a law of a State or Territory	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
2	pharmacists	the manufacture of therapeutic goods, if: (a) the goods are not biologicals; and (b) the goods are produced by the pharmacist: (i) in a pharmacy where the pharmacist practices and the pharmacy is open to the public; or (ii) on the premises of a dispensary conducted by a Friendly Society; or (iii) on the premises of a private hospital; and (c) the goods are for supply (other than by wholesale) on or from those premises
3	biomedical engineers, radiochemists and pharmacists in public hospitals	the manufacture of therapeutic goods, other than biologicals, by the person when employed by a public hospital or a public institution and produced by that person for supply in hospitals or public institutions in the same State or Territory
4	herbalists, nutritionists, naturopaths, practitioners of traditional Chinese medicine or homoeopathic practitioners engaged in the manufacture of any herbal, homoeopathic or nutritional supplement preparation	where the preparation is for use in the course of his or her business and: (a) the preparations are manufactured on premises that the person carrying on the business occupies and that he or she is able to close so as to exclude the public; and (b) the person carrying on the business: (i) supplies the preparation for administration to a particular person after consulting with that person; and (ii) uses his or her own judgment as to the treatment required
5	a person who applies supplementary labelling to a manufactured product	the application of supplementary labelling, where the supplementary label contains only a name and address, the registration or listing number of goods, or the biological number of a biological
6	a person who re-labels a product to comply with the labelling	the application of the new label

Column 1 Item	Column 2 Persons	Column 3 Matter in relation to which person exempted
	requirements of the Standard for the Uniform Scheduling of Drugs and Poisons (commonly known as "the Poisons Standard")	
7	charities	the manufacture of packs mentioned in item 14 of Schedule 5A

Schedule 9—Fees—therapeutic goods other than biologicals

(regulation 43)

Part 1—Interpretation

1 Definitions

(1) In this table:

C1 (section 9D) application means a request made under subsection 9D(1), (2) or (3) of the Act to vary information included in an entry in the Register for a registered OTC medicine, that is made in accordance with a form, and in the manner, approved by the Secretary under subsection 9D(6) of the Act for a C1 (section 9D) application.

C1 (section 23) application means an application made under section 23 of the Act to register an OTC medicine that is made in accordance with the form, or in the manner, approved by the Secretary under paragraph 23B(2)(a) of the Act for a C1 (section 23) application.

C2 (section 9D) application means a request made under subsection 9D(3) of the Act to vary information included in an entry in the Register for a registered OTC medicine, that is made in accordance with a form, and in the manner, approved by the Secretary under subsection 9D(6) of the Act for a C2 (section 9D) application.

C2 (section 23) application means an application made under section 23 of the Act to register an OTC medicine that is made in accordance with the form, or in the manner, approved by the Secretary under paragraph 23B(2)(a) of the Act for a C2 (section 23) application.

C3 (section 9D) application means a request made under subsection 9D(3) of the Act to vary information included in an entry in the Register for a registered OTC medicine, that is made in accordance with a form, and in the manner, approved by the Secretary under subsection 9D(6) of the Act for a C3 (section 9D) application.

C3 (section 23) application means an application made under section 23 of the Act to register an OTC medicine that is made in accordance with the form, or in the manner, approved by the Secretary under paragraph 23B(2)(a) of the Act for a C3 (section 23) application.

C4 (section 9D) application means a request made under subsection 9D(3) of the Act to vary information included in an entry in the Register for a registered OTC medicine, that is made in accordance with a form, and in the manner, approved by the Secretary under subsection 9D(6) of the Act for a C4 (section 9D) application.

Clause 1

C4 (section 23) application means an application made under section 23 of the Act to register an OTC medicine that is made in accordance with the form, or in the manner, approved by the Secretary under paragraph 23B(2)(a) of the Act for a C4 (section 23) application.

haematopoietic progenitor cells means primitive pluripotent haematopoietic cells capable of self-renewal as well as maturation into any of the haematopoietic lineages, including committed and lineage-restricted progenitor cells.

major variation, for therapeutic goods of a particular kind, means a change to:

(a) the strength, as recorded in the entry in the Register; or
(b) the dosage, the recommended dose regimen or the maximum daily dose; or
(c) the dosage form; or
(d) the route of administration; or
(e) the intended patient group.

minor variation, for therapeutic goods of a particular kind, means a change (other than a change that is a major variation) to:

(a) the formulation, composition or design specification; or
(b) the container for the goods; or
(c) any other attribute of the goods that results in the goods being separate and distinct.

N1 application means an application made under section 23 of the Act to register an OTC medicine that is made in accordance with the form, or in the manner, approved by the Secretary under paragraph 23B(2)(a) of the Act for an N1 application.

N2 application means an application made under section 23 of the Act to register an OTC medicine that is made in accordance with the form, or in the manner, approved by the Secretary under paragraph 23B(2)(a) of the Act for an N2 application.

N3 application means an application made under section 23 of the Act to register an OTC medicine that is made in accordance with the form, or in the manner, approved by the Secretary under paragraph 23B(2)(a) of the Act for an N3 application.

N4 application means an application made under section 23 of the Act to register an OTC medicine that is made in accordance with the form, or in the manner, approved by the Secretary under paragraph 23B(2)(a) of the Act for an N4 application.

N5 application means an application made under section 23 of the Act to register an OTC medicine that is made in accordance with the form, or in the manner, approved by the Secretary under paragraph 23B(2)(a) of the Act for an N5 application.

new chemical entity means:

(a) a chemical, biological or radiopharmaceutical substance that has not previously been included in the Register; or

(b) an isomer, mixture of isomers, complex of, derivative of or salt of, a registered chemical substance that, having previously been included in the Register, differs from the registered substance in having different safety or efficacy properties; or

(c) a biological substance that, having previously been included in the Register, differs from the registered substance:

(i) in having a different molecular structure; or

(ii) in deriving from source material of a different nature or from a different manufacturing process; or

(d) a radiopharmaceutical substance that:

(i) is a radionucleide or ligand that has not previously been included in the Register; or

(ii) has a coupling mechanism, linking the molecule and radionucleide, that has not previously been included in the Register; or

(e) a fixed combination of active substances that have not previously been included in the Register as that fixed combination.

page means:

(a) a legible photocopy of 1 side of 1 leaf of a published work, diagram or chart; or

(b) in respect of any other work—1 side of 1 leaf (or a copy of 1 side of 1 leaf):

(i) that has a maximum length of 297 millimetres and a maximum width of 210 millimetres; and

(ii) that has a left-hand margin that is at least 25 millimetres in width; and

(iii) the information on which is typed or printed in legible characters at least 8 points in size; and

(iv) that, if it is part of a document exceeding 1 page in length—is paginated.

primary site means the principal manufacturing premises in the capital city of each State and Territory where human blood and blood components are manufactured.

(2) For paragraph (a) of item 2A and items 2B, 2C, 2CA and 4 in Part 2, an application for registration, or variation of the registration, of therapeutic goods of a kind mentioned in Part 1 of Schedule 10 is taken to be a ***submission***.

(3) A person making more than 1 application of a kind mentioned in subclause (2), simultaneously, is taken to be making a ***submission*** that includes all of those applications if the goods concerned contain the same active ingredient.

2 Part 2 fees do not apply in relation to applications etc. covered by Part 3 or 4

The fees prescribed in Part 2 do not apply in relation to applications, evaluations and requests covered by Part 3 or 4.

Part 2—Table of fees other than for applications etc. covered by Part 3 or 4

3 Table of fees

The following table sets out particular fees other than fees for applications, evaluations and requests covered by Part 3 or 4.

Column 1 Item	Column 2 Matter	Column 3 Fee $
1A	Application fee for processing an application for consent under section 14 or 14A of the Act:	
	(a) for an application relating to goods to which a single entry in the Register relates	540 (for all the goods to which the application relates)
	(b) for an application relating to goods to which both of the following apply: (i) there are separate entries in the Register in relation to the goods; (ii) the way in which the goods do not conform with a standard applicable to the goods is the same for all the goods	540 for the first entry plus 108 for each additional entry
1	Evaluation fee for the purposes of subparagraph 19(2)(b)(iii) of the Act	
	(a) if: (i) the goods are medicines for use solely for experimental purposes in humans; and (ii) the evaluation consists of the consideration of: (A) a summary of chemical, pharmaceutical and biological information about the goods; and (B) descriptive information about the proposed clinical trial of the goods; and (C) information about adverse events associated with the use of the goods; and (D) information about the goods provided to the relevant ethics committee; —for each medicine	1,954
	(b) if the goods are medicines for use solely for experimental purposes in humans (other than medicines to which paragraph (a) applies)—for each medicine	24,285
1AAA	Fee for the purposes of paragraph 19(4B)(e) of the Act, for a request under subsection 19(4B) to vary the therapeutic goods specified in an approval to use those goods solely for experimental purposes in humans, or to vary the conditions of such an approval:	
	(a) if the request relates to:	537

Column 1 Item	Column 2 Matter	Column 3 Fee $
	(i) goods that are medicines; and (ii) paragraph (a) of item 1 applied to the evaluation of the application for approval	
	(b) if the request relates to: (i) goods that are medicines; and (ii) paragraph (b) of item 1 applied to the evaluation of the application for approval	6,628
1AA	Application fee for the purposes of paragraph 22C(2)(b) of the Act for an application under subsection 22C(1) of the Act	14,140
1AB	Application fee for the purposes of paragraph 22E(4)(c) of the Act for an application under subsection 22E(3) of the Act	5,127
1ABA	Fee for the purposes of paragraph 22G(8)(b) of the Act for a request under section 22G of the Act	9,347
1AC	Application fee for the purposes of paragraph 23B(2)(b) of the Act for an application under section 23 of the Act for registration of a medicine in relation to which a provisional determination under section 22D of the Act is in force:	
	(a) if the application relates to a new prescription medicine	54,399
	(b) if the application relates to a new indications medicine	32,489
1AD	Evaluation fee for the purposes of subsection 24(1A) of the Act for an application under section 23 of the Act for registration of a medicine in relation to which a provisional determination under section 22D of the Act is in force:	
	(a) if the evaluation relates to a new prescription medicine	283,870
	(b) if the evaluation relates to a new indications medicine	187,268
1AE	Application fee for the purposes of paragraph 23B(2)(b) of the Act for an application under section 23 of the Act for registration of a medicine that is provisionally registered to be included in the part of the Register for goods known as registered goods	32,381
1AF	Evaluation fee for the purposes of subsection 24(1A) of the Act for an application under section 23 of the Act for registration of a medicine that is provisionally registered to be included in the part of the Register for goods known as registered goods	136,538
1AG	Application fee for the purposes of paragraph 29(5)(d) of the Act for an application under subsection 29(4) of the Act	19,537
1B	Application fee for the purposes of paragraph 25AAA(3)(d) of the Act for therapeutic goods (priority applicant) determination in relation to a medicine	14,140
2	Application fee for the purposes of paragraph 23B(2)(b) of the Act for registration of therapeutic goods (if regulation 43A does not apply):	
	(ba) for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (a) of item 4	54,292
	(bb) for an application relating to a medicine in relation to	18,025

Clause 3

Column 1 Item	Column 2 Matter	Column 3 Fee $
	which an evaluation fee is payable under subparagraph (aa)(i) or (ii) of item 4	
	(bc) for an application relating to a medicine in relation to which an evaluation fee is payable under subparagraph (aa)(iii) of item 4	36,158
	(bca) for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (ab) of item 4	57,530
	(bd) for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (b) of item 4	32,381
	(be) for an application relating to a medicine in relation to which an evaluation fee is payable under subparagraph (bb)(i) or (ii) of item 4 for an evaluation of:	
	(i) an extension of indications	10,761
	(ii) a major variation	7,026
	(bf) for an application relating to a medicine in relation to which an evaluation fee is payable under subparagraph (bb)(iii) of item 4 for an evaluation of:	
	(i) an extension of indications	21,695
	(ii) a major variation	14,032
	(bfa) for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (bd) of item 4	34,215
	(bg) for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (c) of item 4	20,939
	(bh) for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (d) of item 4	3,421
	(bi) for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (g) of item 4	21,156
	(bj) for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (h) of item 4	1,241
	(bk) for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (bc) of item 4	1,241
	(c) subject to paragraph (d), for an application in any other case	4,943
	(d) if a person submits more than one application at the same time and: (i) the additional application is in relation to goods that contain the same therapeutically active ingredient; and (ii) the information in support of each application is sufficiently common in respect of the goods to enable a simultaneous evaluation of the goods to be made	2,461—for each additional application, up to a maximum amount payable of 14,356 (including the fee payable under paragraph (c))

Column 1 Item	Column 2 Matter	Column 3 Fee $
2A	Fee for varying an entry in the Register (not including evaluation of data) under section 9D (other than subsection 9D(2C)) of the Act, if the variation is for:	
	(a) a registered medicine that is mentioned in Part 1 of Schedule 10—for each submission	1,900
	(b) a listed medicine	474
	(c) a disinfectant	1,400
	(d) a Class 3 or Class 4 IVD medical device that is not covered by paragraph (g)	1,750
	(e) an IVD medical device that is not: (i) a Class 3 or Class 4 IVD medical device; and (ii) covered by paragraph (g)	1,000
	(f) a medical device that is not: (i) an IVD medical device; and (ii) covered by paragraph (g)	1,000
	(g) a medical device, if the following are satisfied: (i) the reason for the variation is that the kind of medical device is ***affected by the EU transition*** (within the meaning of subregulation 9.1AA(3) of the *Therapeutic Goods (Medical Devices) Regulations 2002*); (ii) the variation only relates to an update to the manufacturer's evidence for the medical device recorded in the entry in the Register for that kind of medical device; (iii) the request is to vary one or more entries in the Register and the manufacturer's evidence to which the update relates is the same for each of the entries	190 per 10 entries (or part thereof)
2AC	Application fee for an application under subsection 9D(3) of the Act to which regulation 16D applies	1,241
2B	Evaluation fee in relation to an application under subsection 9D(3) of the Act to which regulation 16F applies, for the evaluation of data—for each submission	6,195
2C	Evaluation fee in relation to an application under subsection 9D(3) of the Act to which regulation 16D applies, for the evaluation of data—for each submission	4,954
2CA	Evaluation fee in relation to an application under subsection 9D(2) of the Act, for the evaluation of data—for each submission	6,195
2CB	Fee for a request under subsection 9D(2C) of the Act (other than a request to which item 2CC, 2CD or 2CE applies) to make one or more variations of one or more entries in the Register in relation to a medicine:	
	(a) for each entry, unless paragraph (b) applies	907
	(b) in the case of a single entry in the Register, if the request is made together with a request of a kind mentioned in item 5	Nil

Clause 3

Column 1 Item	Column 2 Matter	Column 3 Fee $
	of Part 3 in relation to the same entry	
2CC	Fee for a request under subsection 9D(2C) of the Act to make the same variation or variations of 2 or more entries in the Register that each relate to a registered complementary medicine—for each group of up to 7 entries	907
2CD	Fee for a request under subsection 9D(2C) of the Act to make the same variation or variations of 2 or more entries in the Register that each relate to a registered OTC medicine:	
	(a) for each group of up to 7 entries, unless paragraph (b) applies	907
	(b) for each group of up to 20 entries, if the request is made together with a request of a kind mentioned in item 5 of Part 3, in relation to the same group of entries	Nil
2CE	Fee for a request under subsection 9D(2C) of the Act to make the same variation or variations of 2 or more entries in the Register if: (a) each entry relates to a prescription medicine or a biological medicine; and (b) 2 or more of those medicines have the same active ingredient	The sum of: (a) for each group of entries relating to medicines with the same active ingredient—907; and (b) for any other entry—907
3	Application fee for paragraph 23C(2)(c) of the Act for the listing of therapeutic goods (other than for an application to which regulation 43A applies) if the goods are:	
	(a) a disinfectant	2,200
	(b) a medicine	939
3AB	Fee for a notice and declaration under subregulation 43AAE(2) relating to an exemption from liability to pay an annual registration charge, annual listing charge or annual charge for inclusion in the Register in respect of therapeutic goods for a financial year:	
	(a) if the notice and declaration relate to not more than 5 entries in the Register	474
	(b) if the notice and declaration relate to 6 or more entries in the Register	474 for the first 5 entries plus 54 for each additional entry
4	Evaluation fee, for subsection 24(1A) of the Act, under a submission for evaluation relating to:	
	(a) a new chemical entity (other than an entity to which paragraph (aa) or (ab) of this item, paragraph (a) of item 1AD or item 1AF applies)	217,598
	(aa) a new chemical entity incorporated as an ancillary medicinal component of a medical device if the evaluation of the new chemical entity involves an evaluation of:	

Column 1 Item	Column 2 Matter	Column 3 Fee $
	(i) documentation setting out the chemistry, quality control and manufacturing of the new chemical entity; or	72,641
	(ii) documentation relating to pre-clinical studies; or	72,641
	(iii) documentation mentioned in subparagraphs (i) and (ii)	144,742
	(ab) a new prescription medicine in relation to which a therapeutic goods (priority applicant) determination is in force	230,118
	(b) an extension of indications (other than an extension of indications to which paragraph (bb), (bc) or (bd) of this item, paragraph (b) of item 1AD or item 1AF applies)	129,091
	(bb) an extension of indications or a major variation in respect of a medicine incorporated as an ancillary medicinal component of a medical device if the evaluation of the medicine involves an evaluation of:	
	(i) documentation setting out the chemistry, quality control and manufacturing of the medicine; or	for an evaluation relating to: (a) an extension of indications—43,066 (b) a major variation—27,955
	(ii) documentation relating to pre-clinical studies; or	for an evaluation relating to: (a) an extension of indications—43,066 (b) a major variation—27,955
	(iii) documentation mentioned in subparagraphs (i) and (ii)	for an evaluation relating to: (a) an extension of indications—86,024 (b) a major variation—56,235
	(bc) an extension of indications that is the subject of an application to which regulation 16G applies	4,954
	(bd) a new indications medicine in relation to which a therapeutic goods (priority applicant) determination is in force	136,862
	(c) a new generic product	83,110
	(d) an additional trade name	13,600
	(g) a major variation (that is not a variation mentioned in any of paragraphs (a) to (d))	84,189
	(h) a minor variation (that is not a variation mentioned in any of paragraphs (a) to (d))	4,954

Clause 3

Column 1 Item	Column 2 Matter	Column 3 Fee $
6AA	Fee for processing of data in relation to goods, a step in the manufacture of which was carried out outside Australia (in addition to any other fee prescribed in this Schedule in relation to the application) to determine whether the manufacturing and quality control procedures used in the manufacture of the goods are acceptable: (a) for the purposes of subsection 9D(1), (2) or (3) of the Act; or (b) for the purposes of paragraph 25(1)(g), 26(1)(g), 31(1)(e) or 31(2)(d) of the Act	723
6AB	Fee for Department obtaining evidence from overseas regulatory authority of the manufacturing and quality control procedures used in the manufacture of goods, a step in the manufacture of which was carried out outside Australia (in addition to fee prescribed in item 6AA)	777
6ABA	Fee for desk audit of overseas compliance certification to identify third party certifications and review the overseas compliance certification by examining the underlying audit report and obtaining information from the overseas regulators	2,764
6AC	Fee for reinstatement of acceptance status of data relating to the manufacturing and quality control procedures used in the manufacture of goods, a step in the manufacture of which was carried out outside Australia (in addition to fee prescribed in items 6AA and 6ABA)	1,306
6B	Fee for evaluation of data, under subsection 9D(1), (2) or (3) of the Act, about an entry in the Register relating to disinfectants	4,155
6BA	Application fee for a request, under subsection 30A(1) of the Act, for the revocation of the cancellation of the registration or listing of therapeutic goods from the Register: (a) if the request relates to one registration or listing; (b) if the request relates to more than one registration or listing	 173 173 for the first registration or listing plus 54 for each additional registration or listing
6BB	Application fee for a request, under subsection 30AA(1) of the Act, for the revocation of the cancellation of the registration or listing of therapeutic goods: (a) if the request relates to one registration or listing; (b) if the request relates to more than one registration or listing	 173 173 for the first registration or listing plus 54 for each additional registration or listing
6C	Fee for evaluating documents and other information, relating to the safety of a medicine, obtained under paragraph 31(2)(f) of	9,023

Column 1 Item	Column 2 Matter	Column 3 Fee $
	the Act (other than an evaluation to which item 6D applies)	
6D	Fee for evaluating documents and other information, relating to the safety, quality and efficacy of a medicine, obtained under paragraphs 31(2)(f) and (h) of the Act, if the total number of pages of the evaluation documentation is:	
	(a) not over 50 pages	11,873
	(b) over 50 pages, but not over 250 pages	15,327
	(c) over 250 pages, but not over 500 pages	20,939
	(d) over 500 pages, but not over 1 000 pages	27,739
	(e) over 1 000 pages, but not over 2 000 pages	41,555
	(f) over 2 000 pages, but not over 3 000 pages	55,371
	(g) over 3 000 pages	83,110
7A	Fee for evaluation under paragraph 16GA(1)(a):	
	(a) if the evaluation documentation does not contain clinical or toxicological information	11,873
	(b) if the evaluation documentation contains clinical or toxicological information, and the total number of pages is:	
	(i) not over 50 pages	11,873
	(ii) over 50 pages, but not over 250 pages	15,327
	(iii) over 250 pages, but not over 500 pages	20,939
	(iv) over 500 pages, but not over 1 000 pages	27,739
	(v) over 1 000 pages, but not over 2 000 pages	41,555
	(vi) over 2 000 pages, but not over 3 000 pages	55,371
	(vii) over 3 000 pages	83,110
7B	Fee for evaluation, under paragraph 16GA(1)(b), in relation to 1 or more new excipients for use in particular therapeutic goods:	
	(a) if the evaluation documentation does not contain clinical or toxicological information	11,873
	(b) if the evaluation documentation contains clinical or toxicological information, and the total number of pages is:	
	(i) not over 50 pages	11,873
	(ii) over 50 pages, but not over 250 pages	15,327
	(iii) over 250 pages, but not over 500 pages	20,939
	(iv) over 500 pages, but not over 1 000 pages	27,739
	(v) over 1 000 pages, but not over 2 000 pages	41,555
	(vi) over 2 000 pages, but not over 3 000 pages	55,371
	(vii) over 3 000 pages	83,110
7C	Application fee for the purposes of paragraph 26BJ(2)(d) of the Act	1,176
8	(a) Application fee for the purposes of paragraph 37(1)(g) of the Act, for a licence for:	885
	(i) the manufacture of therapeutic goods; or	

Clause 3

Column 1 Item	Column 2 Matter	Column 3 Fee $
	(ii) one or more steps in the manufacture of therapeutic goods; or (iii) the manufacture of ingredients or components for use in the manufacture of therapeutic goods; or (iv) the manufacture of herbal or homoeopathic preparations; unless paragraph (b) applies	
	(b) Application fee for the purposes of paragraph 37(1)(g) of the Act, for a licence for: (i) the manufacture of haematopoietic progenitor cells; or (ii) the manufacture of human blood and blood components (other than haematopoietic progenitor cells)	1,155
8A	Application fee for the purposes of paragraph 40B(2)(g) of the Act, for an application under subsection 40B(1) of the Act (addition of manufacturing sites) for the variation of a licence to which paragraph (a) of item 8 applies	855
8B	Application fee for the purposes of paragraph 40B(7)(d) of the Act, for an application under subsection 40B(6) of the Act for the variation of the manufacturing site authorisation in relation to a licence to which paragraph (a) of item 8 applies	855
8C	Application fee for the purposes of paragraph 40B(9B)(c) of the Act, for an application under subsection 40B(9A) of the Act (removal of manufacturing sites) for the variation of a licence to which paragraph (a) of item 8 applies	855
9	(a) Fee for paragraphs 38(1)(c) and 58(3)(b) of the Act for inspection within Australia (except for therapeutic goods mentioned in items 9AA, 9AB, 9AC and 9ACA), per hour, per inspector, for: (i) the manufacture of therapeutic goods; or (ii) one or more steps in the manufacture of therapeutic goods; or (iii) the manufacture of ingredients or components for use in the manufacture of therapeutic goods; or (iv) the manufacture of herbal or homoeopathic preparations	1,101
	(b) Fee for inspection outside Australia, per hour, per inspector, for inspection of a kind mentioned in paragraph (a)	1,543
9AA	Fee for inspection (including an inspection for paragraph 58(3)(b) of the Act) of manufacturing premises or operations for the preparation of haematopoietic progenitor cells under licence, for each inspector engaged per hour, or part of an hour	755
9AB	Fee for inspection (including an inspection for paragraph 58(3)(b) of the Act) of manufacturing premises or operations for the preparation of human blood and blood	1,026

Column 1 Item	Column 2 Matter	Column 3 Fee $
	components (other than haematopoietic progenitor cells) under licence, at the primary site covered by the licence, for each inspector engaged per hour, or part of an hour	
9AC	Fee for inspection (including an inspection for paragraph 58(3)(b) of the Act) of manufacturing premises or operations for the preparation of human blood and blood components (other than haematopoietic progenitor cells) under licence, at a site covered by the licence (other than a site to which item 9AB applies), for each inspector engaged per hour, or part of an hour	755
9ACA	Fee for inspection (including an inspection for paragraph 58(3)(b) of the Act) of manufacturing premises or operations for the preparation of human tissues under licence, for each inspector engaged per hour, or part of an hour	755
9AD	Fee for paragraph 25(1)(g) or (h), or 26(1)(g) or (h) of the Act (and, in relation to associated inspections, for paragraphs 38(1)(c), 41(1)(f) and 58(3)(b) of the Act), in respect of the evaluation of the manufacture of human blood and blood components prepared under licence by reference to data contained in files known as technical master files or plasma master files, where the total number of pages of each file referred to is:	
	(a) not over 10 pages	1,490
	(b) over 10 pages, but not over 50 pages	12,628
	(c) over 50 pages, but not over 100 pages	28,494
	(d) over 100 pages, but not over 1 000 pages	38,317
	(e) over 1 000 pages, but not over 3 000 pages	59,688
	(f) over 3 000 pages, but not over 4 000 pages	79,548
	(g) over 4 000 pages	97,033
9D	Fee for evaluation, under subsection 9D(1), (2) or (3), subsection 24(1A) or paragraph 26(1)(d) of the Act, of data relating to the device component, to which Chapter 4 of the Act applies, of a medicine (in addition to the fee prescribed in item 4, or in Part 3 of this Schedule, for evaluating the medicine)	The fee applicable, under item 1.9, 1.10, 1.12 or 1.16 (and, if applicable, clause 2.2) of Schedule 5 to the *Therapeutic Goods (Medical Devices) Regulations 2002*, to the kind of work to be undertaken
10	Fee for an application for certification under paragraph 58(3)(a) of the Act	195 multiplied by the number of certifications sought in the application
11	Fee for the inspection of manufacturing operations other than for the purposes of Part 3-3 of the Act	The fee applicable under item 9 for that step of manufacture

Clause 3

Column 1 Item	Column 2 Matter	Column 3 Fee $
12	Fee for evaluation of data in relation to therapeutic goods specified in Schedule 10 for the purposes of subsection 9D(1), (2) or (3) of the Act that is not covered by another item in this Part	The fee applicable under item 1, 4 or 5 for an evaluation of that nature
13	Fee for an evaluation under subsection 66(4) of the Act	The fee applicable under item 1, 4 or 5 for an evaluation of that nature
14	Fee for notification required under item 3 of Schedule 5A:	
	(a) of intention to sponsor a clinical trial at a trial site using a specified medicine	410
	(b) for each notification of an additional trial site or additional trial sites	410
16	Fee, including deposit, for an application under subsection 61(6) of the Act	The amount, including a deposit, that would be payable under the *Freedom of Information Act 1982* and the Freedom of Information (Fees and Charges) Regulations for a request if the application were a request under section 15 of that Act
18	Fee for providing advice in relation to a prescription medicine at the request of the sponsor of the medicine for the purpose of listing the medicine as a pharmaceutical benefit	2,504

Part 3—Table of fees for applications etc. in relation to certain OTC medicines

4 Table of fees

The following table sets out particular fees for applications, evaluations and requests in relation to OTC medicines that are, or are to be, registered goods.

Fees		
Column 1 **Item**	**Column 2** **Matter**	**Column 3** **Fee $**
1	Application fee under paragraph 23B(2)(b) of the Act:	
	(a) for an N1 application	1,835
	(b) for an N2 application	1,835
	(c) for an N3 application	2,947
	(d) for an N4 application	4,307
	(e) for an N5 application	6,379
	(f) for a C1 (section 23) application	1,835
	(g) for a C2 (section 23) application	1,835
	(h) for a C3 (section 23) application	1,835
	(i) for a C4 (section 23) application	2,947
2	Evaluation fee under subsection 24(1A) of the Act:	
	(a) for an N1 application	4,533
	(b) for an N2 application	6,444
	(c) for an N3 application	9,930
	(d) for an N4 application	16,514
	(e) for an N5 application	24,285
	(f) for a C2 (section 23) application	4,533
	(g) for a C3 (section 23) application	7,609
	(h) for a C4 (section 23) application	9,930
3	If, at the time a person submits an application of a kind mentioned in paragraph (a), (b), (c), (d) or (e) of item 1: (a) the person also submits an additional application or applications of the same kind; and (b) each application relates to goods that contain the same therapeutically active ingredient; and (c) the information in support of each application is sufficiently common in respect of the goods to enable a simultaneous assessment of the goods to be made; the application fee under paragraph 23B(2)(b) of the Act for each additional application is:	

Clause 4

Fees		
Column 1 **Item**	**Column 2** **Matter**	**Column 3** **Fee $**
	(d) for an additional N1 application	928
	(e) for an additional N2 application	928
	(f) for an additional N3 application	1,479
	(g) for an additional N4 application	1,479
	(h) for an additional N5 application	1,479
4	If, at the time a person submits an application of a kind mentioned in paragraph (c), (d) or (e) of item 2: (a) the person also submits an additional application or applications of the same kind; and (b) each application relates to goods that contain the same therapeutically active ingredient; and (c) the information in support of each application is sufficiently common in respect of the goods to enable a simultaneous evaluation of the goods to be made; the evaluation fee under subsection 24(1A) of the Act for each additional application is:	
	(d) for an additional N3 application	5,030
	(e) for an additional N4 application	5,030
	(f) for an additional N5 application	5,030
5	Application fee under paragraph 9D(7)(f) of the Act, for any of the following requests in relation to up to 20 entries in the Register:	
	(a) a C1 (section 9D) application	1,835
	(b) a C2 (section 9D) application	6,379
	(c) a C3 (section 9D) application	9,455
	(d) a C4 (section 9D) application	12,844
7	Fee for providing advice in relation to a registered OTC medicine at the request of the sponsor of the medicine for the purpose of listing the medicine as a pharmaceutical benefit:	
	(a) if the request does not contain clinical data	1,802
	(b) if the request contains clinical data or a justification as to why such data is not needed	9,240

Part 4—Table of fees for applications etc. in relation to certain complementary medicines and certain other listed medicines

5 Table of fees

The following table sets out particular fees for applications, evaluations and requests in relation to certain medicines.

Fees		
Item	**Column 1** **Matter**	**Column 2** **Fee $**
1A	Application fee under paragraph 9D(7)(f) of the Act for an L(A)C1 (section 9D) request	2,212
1B	Application fee under paragraph 9D(7)(f) of the Act for an L(A)C2 (section 9D) request	9,661
1C	Application fee under paragraph 9D(7)(f) of the Act for an L(A)CN (section 9D) request	885
1D	Application fee under paragraph 23B(2)(b) of the Act for an L(A)C1 (section 23) application	1,026
1E	Application fee under paragraph 23B(2)(b) of the Act for an L(A)C2 (section 23) application	1,026
1F	Application fee under paragraph 23B(2)(b) of the Act for an L(A)CN (section 23) application	885
1G	Evaluation fee under subsection 26AC(2) of the Act for an L(A)C1 (section 23) application	1,188
1H	Evaluation fee under subsection 26AC(2) of the Act for an L(A)C2 (section 23) application	8,635
1	Application fee under paragraph 9D(7)(f) of the Act for an RCMC1 (section 9D) request	1,609
2	Application fee under paragraph 9D(7)(f) of the Act for an RCMC2 (section 9D) request	5,429
3	Application fee under paragraph 9D(7)(f) of the Act for an RCMC3 (section 9D) request	8,063
4	Application fee under paragraph 9D(7)(f) of the Act for an RCMC4 (section 9D) request	11,442
5	Application fee under paragraph 23B(2)(b) of the Act for an RCMC1 (section 23) application	1,609
6	Application fee under paragraph 23B(2)(b) of the Act for an RCMC2 (section 23) application	842
7	Evaluation fee under subsection 24(1A) of the Act for an RCMC2 (section 23)	4,576

Clause 5

Fees

Item	Column 1 Matter	Column 2 Fee $
	application	
8	Application fee under paragraph 23B(2)(b) of the Act for an RCMC3 (section 23) application	907
9	Evaluation fee under subsection 24(1A) of the Act for an RCMC3 (section 23) application	7,167
10	Application fee under paragraph 23B(2)(b) of the Act for an RCMC4 (section 23) application	928
11	Evaluation fee under subsection 24(1A) of the Act for an RCMC4 (section 23) application	10,588
12	Application fee under paragraph 23B(2)(b) of the Act for an RCM1 application	615
13	Evaluation fee under subsection 24(1A) of the Act for a RCM1 application	3,529
14	Application fee under paragraph 23B(2)(b) of the Act for an RCM2 application	2,212
15	Evaluation fee under subsection 24(1A) of the Act for a RCM2 application	23,637
16	Application fee under paragraph 23B(2)(b) of the Act for an RCM3 application	2,212
17	Evaluation fee under subsection 24(1A) of the Act for a RCM3 application	23,637
18	Application fee under paragraph 23B(2)(b) of the Act for an RCM4 application	2,925
19	Evaluation fee under subsection 24(1A) of the Act for a RCM4 application	32,165
20	Application fee under paragraph 23B(2)(b) of the Act for an RCM5 application	3,205
21	Evaluation fee under subsection 24(1A) of the Act for a RCM5 application	41,015
22	Application fee under paragraph 23B(2)(b) of the Act for an L(A)1 application	497
23	Evaluation fee under subsection 26AC(2) of the Act for an L(A)1 application	1,889
24	Application fee under paragraph 23B(2)(b) of the Act for an L(A)2 application	2,040
25	Evaluation fee under subsection 26AC(2) of the Act for an L(A)2 application	15,651
26	Application fee under paragraph 23B(2)(b) of the Act for an L(A)3 application	2,040
27	Evaluation fee under subsection 26AC(2) of the Act for an L(A)3 application	15,651
28	Application fee under paragraph 26BD(3)(c) of the Act for an IN1 application	1,209
29	Evaluation fee under paragraph 26BE(3)(b) of the Act for an IN1 application	16,299
30	Application fee under paragraph 26BD(3)(c) of the Act for an IN2 application	1,209
31	Evaluation fee under paragraph 26BE(3)(b) of the Act for an IN2 application	16,299
32	Application fee under paragraph 26BD(3)(c) of the Act for an IN3 application	3,205
33	Evaluation fee under paragraph 26BE(3)(b) of the Act for an IN3 application	26,552
34	Application fee under paragraph 26BD(3)(c) of the Act for an IN4 application	3,205
35	Evaluation fee under paragraph 26BE(3)(b) of the Act for an IN4 application	26,552

Schedule 9A—Fees—biologicals

(regulation 43)

Part 1—Interpretation of table

1 Definitions

In this table:

major variation, for a biological, means a change to the entry of the biological in the Register for any of the following, other than a change that would result in the biological becoming separate and distinct from other biologicals:

(a) a change requiring submission and evaluation of clinical data;

(c) a new strength;

(d) a new route of administration;

(e) a change in the intended patient group;

(f) a change in dosage.

minor variation, for a biological, means a change to the entry of the biological in the Register that requires the evaluation of quality and manufacturing information, other than a change that is a major variation for the biological or that would result in the biological becoming separate and distinct from other biologicals.

Part 2—Table of fees

Item	Matter	Fee
1	Application for inclusion of a Class 1 biological in the Register for paragraph 32DA(2)(d) of the Act	$1,231 for each application
2	Application for inclusion of a Class 2, Class 3 or Class 4 biological in the Register for paragraph 32DDA(2)(b) of the Act	$1,231 for each application
2AA	Application fee for the purposes of paragraph 32DCA(2)(c) of the Act for an application to include an export only biological in the Register	$1,231 for each application
2A	Application fee for the purposes of paragraph 32DEA(3)(d) of the Act for a biologicals (priority applicant) determination in relation to a biological	$14,697
3	Application for a manufacturing licence for paragraph 37(1)(g) of the Act	$1,231 for each application
3A	Fee for a notice and declaration under subregulation 43AAE(2) relating to an exemption from liability to pay an annual charge for inclusion of a biological in the Register for a financial year:	
	(a) if the notice and declaration relate to not more than 5 entries in the Register	$474
	(b) if the notice and declaration relate to 6 or more entries in the Register	$474 for the first 5 entries plus $54 for each additional entry
4	Evaluation of a Class 2 biological for inclusion in the Register for subsection 32DI(1) of the Act:	
	(a) for a biological in relation to which a biologicals (priority applicant) determination is in place	$85,630 for each evaluation
	(b) in any other case	$81,922 for each evaluation
5	Evaluation of a Class 3 biological for inclusion in the Register for subsection 32DI(1) of the Act:	
	(a) for a biological in relation to which a biologicals (priority applicant) determination is in place	$171,683 for each evaluation
	(b) in any other case	$163,953 for each evaluation
6	Evaluation of a Class 4 biological for inclusion in the Register for subsection 32DI(1) of the Act:	
	(a) for a biological in relation to which a biologicals (priority applicant) determination is in place	$277,423 for each evaluation

Item	Matter	Fee
	(b) in any other case	$266,384 for each evaluation
7	Evaluation of an ingredient or component of a biological under regulation 16GF, for use in multiple biologicals (for which application for registration would later be made)	$26,660 for each evaluation
8	Application under subsection 9D(3AA) or (3A) of the Act to vary the entry of a biological in the Register	$1,231 for each application
8A	Evaluation of an application under subsection 9D(3AA) of the Act to vary the entry of a biological in the Register	$7,512 for each evaluation
9	Evaluation of an application under subsection 9D(3A) of the Act to vary the entry of a Class 2 biological in the Register	$7,512 for each evaluation
10	Evaluation of an application under subsection 9D(3A) of the Act to vary the entry of a Class 3 or Class 4 biological in the Register, if the variation is a minor variation	$19,752 for each evaluation
11	Evaluation of an application under subsection 9D(3A) of the Act to vary the entry of a Class 3 or Class 4 biological in the Register, if the variation is a major variation	$38,857 for each evaluation
11A	Application fee for processing an application for consent under section 14 or 14A of the Act:	
	(a) for an application relating to goods that are biologicals to which a single entry in the Register relates	$540 (for all the goods to which the application relates)
	(b) for an application relating to goods that are biologicals to which both of the following apply: (i) there are separate entries in the Register in relation to the goods; (ii) the way in which the goods do not conform with a standard applicable to the goods is the same for all the goods	$540 for the first entry plus $108 for each additional entry
12	Inspection fee—initial manufacturing audit (Australia and overseas) for paragraphs 32DE (1) (e), 38(1)(c) and 58(3)(b) of the Act	$24,285 for each inspection
13	Inspection fee—subsequent Manufacturing Audit (Australia and overseas) for paragraphs 41 (1)(f) and 58(3)(b) of the Act	$18,457 for each inspection
14	Inspection fee—in addition to an inspection fee mentioned in item 12 or 13 above for an inspection that is required to be conducted outside Australia	$755 for each hour of preparation by each inspector
15	Inspection fee—in addition to an inspection fee	Amount of costs and reasonable

Item	Matter	Fee
	mentioned in item 12 or 13 above for an inspection that is required to be conducted outside Australia	expenses of travel by each inspector, including costs for accommodation and allowance outside Australia
16	Evaluation fee for subsection 32CK(4) of the Act	$29,574 for each evaluation
16AA	Fee for the purposes of paragraph 32CK(9A)(e) of the Act, for a request under subsection 32CK(9A) of the Act to vary the biological specified in an approval to use the biological solely for experimental purposes in humans, or to vary the conditions of such an approval	$8,069
16A	Application fee for a request, under subsection 32GD(1) of the Act, for the revocation of the cancellation of an entry of a biological from the Register:	
	(a) if the request relates to one entry;	$173
	(b) if the request relates to more than one entry	$173 for the first entry plus $54 for each additional entry
16B	Application fee for a request, under subsection 32GDA(1) of the Act, for the revocation of the cancellation of an entry of a biological from the Register:	
	(a) if the request relates to one entry;	$173
	(b) if the request relates to more than one entry	$173 for the first entry plus $54 for each additional entry
17	Fee for notification required under item 3 of Schedule 5A for a biological to which that Schedule applies:	
	(a) of intention to sponsor a clinical trial at a trial site using a biological	$410
	(b) for each notification of an additional trial site or additional trial sites	$410

Schedule 10—Therapeutic goods for evaluation

Note: See regulations 16C, 16D, 16F, 16G and 45.

Part 1—Evaluation of prescription and other medicines by the Prescription Medicines Authorisation Branch

Column 1 Item	Column 2 Product
1	therapeutic goods (except therapeutic goods mentioned in another Part of this Schedule), that: (a) contain a substance mentioned in Schedule 4, 8 or 9 to the Poisons Standard; or (b) contain a substance not mentioned in any of those Schedules but which meets the criteria for mention in any of those Schedules
2	a medical gas
3	a vaccine
4	an allergen, except an allergen for skin patch testing on unbroken skin
5	a biotechnology medicine
6	an immunoglobulin
7	a radio contrast agent, except barium sulphate preparation for radiological use
8	a radiopharmaceutical
9	a dialysis solution, except a haemodialysis solution
11	a special dosage form, such as a transdermal system or osmotic pump
12	an injectable medicine dosage form
13	a blood product
14	therapeutic goods referred to the Prescription Medicines Authorisation Branch of the Therapeutic Goods Administration within the Department for the purpose of evaluation as a prescription medicine
15	an excipient in therapeutic goods mentioned in this Part

Part 2—Evaluation of complementary medicines by the Complementary and OTC Medicines Branch

The following therapeutic goods, if the sponsor has satisfied the Secretary that the goods do not meet the criteria for mention in Schedule 4, 8 or 9 of the Poisons Standard:

Column 1 Item	Column 2 Product
1	a complementary medicine
2	an excipient in complementary medicine
3	therapeutic goods referred for evaluation to the Complementary and OTC Medicines Branch of the Therapeutic Goods Administration within the Department

Part 3—Evaluation of non-prescription and other medicines by the Complementary and OTC Medicines Branch

The following therapeutic goods, if the sponsor has satisfied the Secretary that the goods do not meet the criteria for mention in Schedule 4, 8 or 9 of the Poisons Standard:

Column 1 Item	Column 2 Product
1	an antiseptic
2	a sunscreen preparation
3	all other therapeutic goods not mentioned in another Part of this Schedule
4	an excipient in therapeutic goods mentioned in this Part
5	therapeutic goods referred to the Complementary and OTC Medicines Branch of the Therapeutic Goods Administration within the Department for the purpose of evaluation as a non-prescription medicine

Schedule 12—Consumer medicine information documents

Note: See subregulation 9A(1).

1 General requirements

A consumer medicine information document about a medicine must:

(a) be written in English; and

(b) be clearly legible; and

(c) be written in language that will easily be understood by patients; and

(d) be consistent with product information about the product.

2 Specific requirements—document enclosed within packaging etc.

Also, if the consumer medicine information document about a medicine is enclosed within, on a surface of, or affixed to a surface of, the packaging of the medicine, it must set out all of the information required by the "TGA Consumer Medicine Information (Prescription Medicine) Template" (published by the Therapeutic Goods Administration on its website) but:

(a) it is not required to set out the information in the same order as the Template; and

(b) it is not required to include any Consumer Medicine Information (CMI) summary that forms part of that Template.

3 Specific requirements—document not enclosed within packaging etc.

Also, if the consumer medicine information document about a medicine is not enclosed within, on a surface of, or affixed to a surface of, the packaging of the medicine:

(a) it must set out all of the information required by the "TGA Consumer Medicine Information (Prescription Medicine) Template" (published by the Therapeutic Goods Administration on its website) in the same order as the Template; and

(b) if it is supplied in electronic form, it must be in the form of a PDF file or an HTML file.

Schedule 13—Consumer medicine information documents

Note: See subregulation 9A(1A).

1 General requirements

A consumer medicine information document about a medicine must:

(a) be written in English; and

(b) be clearly legible; and

(c) be written in language that will easily be understood by patients; and

(d) be consistent with product information about the product.

2 Specific requirements—document enclosed within packaging etc.

Also, if the consumer medicine information document about a medicine is enclosed within, on a surface of, or affixed to a surface of, the packaging of the medicine, it must set out all of the information required by the "TGA Consumer Medicine Information (Non-prescription Medicine) Template" (published by the Therapeutic Goods Administration on its website) but:

(a) it is not required to set out the information in the same order as the Template; and

(b) it is not required to include any Consumer Medicine Information (CMI) summary that forms part of that Template.

3 Specific requirements—document not enclosed within packaging etc.

Also, if the consumer medicine information document about a medicine is not enclosed within, on a surface of, or affixed to a surface of, the packaging of the medicine:

(a) it must set out all of the information required by the "TGA Consumer Medicine Information (Non-prescription Medicine) Template" (published by the Therapeutic Goods Administration on its website) in the same order as the Template; and

(b) if it is supplied in electronic form, it must be in the form of a PDF file or an HTML file.

Schedule 14—Designated active ingredients

(regulation 2)

Item	Ingredient or kind of ingredient
1	an amino acid
2	charcoal
3	a choline salt
4	an essential oil
5	plant or herbal material (or a synthetically produced substitute for material of that kind), including plant fibres, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll
6	a homoeopathic preparation
7	a microorganism, whole or extracted, except a vaccine
8	a mineral including a mineral salt and a naturally occurring mineral
9	a mucopolysaccharide
10	non-human animal material (or a synthetically produced substitute for material of that kind) including dried material, bone and cartilage, fats and oils and other extracts or concentrates
11	a lipid, including an essential fatty acid or phospholipid
12	a substance produced by or obtained from bees, including royal jelly, bee pollen and propolis
13	a sugar, polysaccharide or carbohydrate
14	a vitamin or provitamin

Schedule 16—Classes of biologicals

Note: See regulation 2.

1A Class 1 biologicals

For the purposes of the definition of ***Class 1 biological*** in regulation 2, a biological is a Class 1 biological if:

(a) it is a faecal microbiota transplant product; and

(b) it is not advertised to consumers; and

(c) it is to be collected under the supervision or direction, or in accordance with the requirements, of a medical practitioner registered, in a State or internal Territory, as a medical practitioner; and

(d) each later step in the manufacture of it is to be carried out in a hospital by, or under the supervision or direction of, the practitioner (unless the step relates to the storage or testing of the biological, in which case it may instead be carried out by a person under a contract with the hospital in a State or internal Territory); and

(e) it is for use in a recipient who is a patient of the hospital with the recipient being under the clinical care of the practitioner.

1 Class 4 biologicals

For the purposes of the definition of ***Class 4 biological*** in regulation 2, the following biologicals are Class 4 biologicals:

(a) biologicals that comprise or contain:

(i) live animal cells; or

(ii) live animal tissues; or

(iii) live animal organs;

(b) biologicals to which both of the following paragraphs apply:

(i) the biologicals comprise, contain or are derived from human cells or human tissues that have been modified to artificially introduce a function or functions of the cells or tissues;

(ii) the artificially introduced function or functions were not intrinsic to the cells or tissues when they were collected from the donor;

(c) pluripotent stem cells;

(d) biologicals derived from pluripotent stem cells.

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.

Editorial changes
The *Legislation Act 2003* authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe how an amendment is to be made. If, despite the misdescription, the amendment can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and "(md not incorp)" is added to 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)

ed = editorial change

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)

underlining = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Number and year	FRLI registration or gazettal	Commencement	Application, saving and transitional provisions
1990 No. 394	6 Dec 1991	15 Feb 1991	
1991 No. 84	30 Apr 1991	rr. 3.1, 5.2, 7.1, 10.2, 11.1, 12.2, 12.4, 13.1 and 14.1: 15 Feb 1991 Remainder: 30 Apr 1991	—
1991 No. 485	24 Dec 1991	24 Dec 1991	—
1992 No. 19	31 Jan 1992	r. 10: 1 July 1992 Remainder: 1 Feb 1992	—
1992 No. 89	14 Apr 1992	14 Apr 1992	—
1992 No. 109	28 Apr 1992	28 Apr 1992	—
1992 No. 332	27 Oct 1992	27 Oct 1992	—
1992 No. 370	30 Nov 1992	30 Nov 1992	—
1992 No. 430	24 Dec 1992	rr. 4 and 7: 1 Jan 1993 Remainder: 24 Dec 1992	—
1993 No. 141	25 June 1993	1 July 1993	—
1994 No. 150	2 June 1994	2 June 1994	r. 22
1994 No. 222	30 June 1994	1 July 1994	—
1994 No. 364	1 Nov 1994	1 Nov 1994	—
1995 No. 33	8 Mar 1995	8 Mar 1995	—
1995 No. 111	31 May 1995	1 June 1995	—
1995 No. 192	30 June 1995	1 July 1995	—
1995 No. 208	4 July 1995	rr. 6 and 9.3: 1 Oct 1995 rr. 8, 9.2, 10.6 and 11.7: 1 Jan 1996 r. 10.7: 1 Oct 1996 rr. 13.2 and 14.4: 1 Jan 1997 Remainder: 4 July 1995	r. 19
1995 No. 253	29 Aug 1995	29 Aug 1995	—
1995 No. 320	3 Nov 1995	3 Nov 1995	—
1995 No. 328	3 Nov 1995	6 Nov 1995 (*see* r. 1 and *Gazette* 1995, No. S423)	—
1996 No. 9	31 Jan 1996	31 Jan 1996	—
1996 No. 25	5 Feb 1996	5 Feb 1996 Note: disallowed by the House of Representatives on 10 Sept 1996	—
1996 No. 131	28 June 1996	1 July 1996	—
1996 No. 200	11 Sept 1996	11 Sept 1996	—
1996 No. 208	26 Sept 1996	26 Sept 1996	—

Endnote 3—Legislation history

Number and year	FRLI registration or gazettal	Commencement	Application, saving and transitional provisions
1997 No. 162	30 June 1997	1 July 1997	—
1997 No. 398	24 Dec 1997	24 Dec 1997	—
1997 No. 399	24 Dec 1997	rr. 1.1, 3.1, 9 and 10: 24 Dec 1997 Remainder: 1 Jan 1998	—
1997 No. 400	24 Dec 1997	24 Dec 1997	—
1997 No. 401	24 Dec 1997	24 Dec 1997 Note: disallowed by the Senate on 31 Mar 1998	—
1998 No. 227	16 July 1998	16 July 1998	—
1998 No. 247	31 July 1998	1 Aug 1998	—
1998 No. 369	22 Dec 1998	1 Jan 1999	—
1999 No. 62	16 Apr 1999	16 Apr 1999	—
1999 No. 209	16 Sept 1999	16 Sept 1999	r. 4
1999 No. 324	16 Dec 1999	16 Dec 1999	—
2000 No. 29	23 Mar 2000	rr. 1, 2 and 3(1) and Schedule 1: 23 Mar 2000 Remainder: 31 Mar 2000	—
2000 No. 48	19 Apr 2000	19 Apr 2000	—
2000 No. 70	12 May 2000	1 July 2000	—
2000 No. 123	22 June 2000	22 June 2000	—
2000 No. 124	22 June 2000	1 July 2000	—
2000 No. 267	28 Sept 2000	28 Sept 2000	—
2000 No. 358	20 Dec 2000	20 Dec 2000	—
2001 No. 159	29 June 2001	29 June 2001	—
2001 No. 160	29 June 2001	1 July 2001	—
2001 No. 252	20 Sept 2001	22 Sept 2001 (*see* r. 2)	—
2001 No. 343	21 Dec 2001	rr. 1–3 and Schedule 1: 30 Sept 2001 Remainder: 21 Dec 2001	—
2002 No. 9	21 Feb 2002	21 Feb 2002	—
2002 No. 84	9 May 2002	9 May 2002	—
2002 No. 114	7 June 2002	7 June 2002	—
2002 No. 143	27 June 2002	1 July 2002	—
2002 No. 234	4 Oct 2002	4 Oct 2002 (*see* r. 2)	—
2002 No. 315	19 Dec 2002	rr. 1–3 and Schedule 1: 19 Dec 2002 Remainder: 1 Jan 2003	—
2002 No. 345	20 Dec 2002	rr. 1–3 and Schedule 1: 20 Dec 2002 Remainder: 1 Jan 2003	—

Endnote 3—Legislation history

Number and year	FRLI registration or gazettal	Commencement	Application, saving and transitional provisions
2003 No. 111	13 June 2003	13 June 2003	—
2003 No. 151	26 June 2003	1 July 2003	—
2003 No. 257	16 Oct 2003	16 Oct 2003	—
2003 No. 258	16 Oct 2003	rr. 1–3 and Schedule 1: 16 Oct 2003 Remainder: 1 Oct 2004	—
2003 No. 301	5 Dec 2003	5 Dec 2003	—
2003 No. 361	23 Dec 2003	23 Dec 2003	—
2004 No. 78	30 Apr 2004	30 Apr 2004	—
2004 No. 127	18 June 2004	1 July 2004	r. 4
2004 No. 159	25 June 2004	1 July 2004	—
2005 No. 192	19 Aug 2005 (F2005L02312)	20 Aug 2005	—
2006 No. 122	2 June 2006 (F2006L01615)	3 June 2006	—
2006 No. 212	10 Aug 2006 (F2006L02573)	11 Aug 2006	—
2007 No. 161	25 June 2007 (F2007L01521)	1 July 2007	—
2008 No. 117	20 June 2008 (F2008L01367)	1 July 2008	—
2009 No. 63	15 Apr 2009 (F200900839)	16 Apr 2009	—
2009 No. 140	25 June 2009 (F2009L01826)	26 June 2009	—
2009 No. 141	25 June 2009 (F2009L02019)	1 July 2009	—
2009 No. 179	9 July 2009 (F2009L02089)	10 July 2009	—
2009 No. 228	10 Sept 2009 (F2009L02935)	11 Sept 2009	—
2009 No. 374	16 Dec 2009 (F2009L04018)	rr. 1–4 and Schedule 1: 1 Jan 2010 Schedule 2: 25 Jan 2010	r. 4
2010 No. 26	3 Mar 2010 (F2010L00470)	1 July 2010	rr. 4–7
2010 No. 129	21 June 2010 (F2010L01285)	1 July 2010	—
2010 No. 130	21 June 2010 (F2010L01282)	1 July 2010	—
2010 No. 266	28 Oct 2010 (F2010L02771)	29 Oct 2010	r. 4
2011 No. 30	16 Mar 2011 (F2011L00434)	31 May 2011 (*see* r. 2)	—
2011 No. 102	21 June 2011 (F2011L01100)	1 July 2011	—
2011 No. 281	8 Dec 2011 (F2011L02595)	rr. 1–3 and Schedule 1: 9 Dec 2011 Schedule 2: 1 Mar 2012	—
2012 No. 142	29 June 2012 (F2012L01448)	30 June 2012	—
2012 No. 143	29 June 2012 (F2012L01455)	1 July 2012	—
2012 No. 251	9 Nov 2012 (F2012L02161)	10 Nov 2012	—
94, 2013	3 June 2013 (F2013L00896)	1 July 2013	—
220, 2013	6 Aug 2013 (F2013L01516)	7 Aug 2013	—
62, 2014	30 May 2014 (F2014L00630)	1 July 2014	—

Endnote 3—Legislation history

Number and year	FRLI registration or gazettal	Commencement	Application, saving and transitional provisions
63, 2014	30 May 2014 (F2014L00632)	1 July 2014	—
75, 2015	1 June 2015 (F2015L00778)	Sch 1 (items 1–6, 9–11): 1 July 2015 (s 2)	—
87, 2015	19 June 2015 (F2015L00854)	Sch 1 (items 2–6): 1 July 2015 (s 2(1) item 1)	—
90, 2015	18 June 2015 (F2015L00837)	Sch 2 (item 197): 1 July 2015 (s 2(1) item 2)	—
213, 2015	1 Dec 2015 (F2015L01909)	1 Jan 2016 (s 2(1) item 1)	—
214, 2015	1 Dec 2015 (F2015L01910)	1 Jan 2016 (s 2(1) item 1)	—

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods Legislation Amendment (Charges Exemptions and Other Measures) Regulation 2016	15 Feb 2016 (F2016L00109)	Sch 1: 1 July 2015 (s 2(1) item 2) Sch 2 and Sch 4 (items 6–35): 16 Feb 2016 (s 2(1) items 3, 5) Sch 4 (items 1–5): 16 Aug 2016 (s 2(1) item 4)	—
Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulation 2016	5 May 2016 (F2016L00667)	Sch 1 (items 2–10): 1 July 2016 (s 2(1) item 1)	—
Therapeutic Goods Amendment (Advisory Committees and Other Measures) Regulation 2016	14 Oct 2016 (F2016L01614)	Sch 1: 1 Jan 2017 (s 2(1) item 2) Remainder: 15 Oct 2016 (s 2(1) items 1, 3)	—
Therapeutic Goods and Other Legislation Amendment (Narcotic Drugs) Regulation 2016	28 Oct 2016 (F2016L01652)	Sch 1 (items 1–8): 1 Nov 2016 (s 2(1) item 2) Note: Sch 1 (items 1, 4) were disallowed by the Senate on 13 June 2017 at 13:07	—
Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2017	19 May 2017 (F2017L00552)	Sch 1 (items 3–5): 1 July 2017 (s 2(1) item 1)	—
Therapeutic Goods Legislation Amendment (2017 Measures No. 1) Regulations 2017	30 June 2017 (F2017L00853)	Sch 1 (items 1–3), Sch 2 (items 7–19), Sch 3–5, Sch 6 (item 2), Sch 7, Sch 8 (items 7–9) and Sch 9: 1 July 2017 (s 2(1) items 2, 4) Sch 1 (items 4–7): 4 Dec 2017 (s 2(1) item 3)	—
as amended by			
Therapeutic Goods Legislation Amendment (2017 Measures No. 2) Regulations 2017	1 Dec 2017 (F2017L01561)	Sch 2 (item 1): 2 Dec 2017 (s 2(1) item 3)	—

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods Legislation Amendment (2017 Measures No. 2) Regulations 2017	1 Dec 2017 (F2017L01561)	Sch 2 (items 2–12): 4 Dec 2017 (s 2(1) item 4) Sch 3: 1 Jan 2018 (s 2(1) item 5) Sch 4 (items 1–4, 6, 11–17): 2 Dec 2017 (s 2(1) item 6)	—
Therapeutic Goods Legislation Amendment (2018 Measures No. 1) Regulations 2018	19 Mar 2018 (F2018L00311)	Sch 1, Sch 2, Sch 4 (items 1–11), Sch 5 and Sch 6 (items 9–42): 20 Mar 2018 (s 2(1) items 2, 3, 5, 8) Sch 4 (items 12–16): 1 July 2020 (s 2(1) item 6) Sch 4 (items 17–23): 1 July 2018 (s 2(1) item 7)	—
Therapeutic Goods Legislation Amendment (Exempt Devices and Goods) Regulations 2018	26 Apr 2018 (F2018L00516)	Sch 1 (items 6–10): 27 Apr 2018 (s 2(1) item 1)	—
Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2018	12 June 2018 (F2018L00759)	Sch 1 (items 5–16): 1 July 2018 (s 2(1) item 2) Sch 1 (items 17, 18): 1 July 2019 (s 2(1) item 3)	—
Therapeutic Goods Legislation Amendment (2018 Measures No. 2) Regulations 2018	25 June 2018 (F2018L00865)	Sch 1 (items 4–29): 1 July 2018 (s 2(1) items 2, 3) Note: This amending title was affected by an editorial change (see F2018C00390)	—
Therapeutic Goods Legislation Amendment (2018 Measures No. 3) Regulations 2018	15 Oct 2018 (F2018L01434)	Sch 1 (items 3–34): 16 Oct 2018 (s 2(1) item 2) Sch 1 (items 37–49): 1 Jan 2019 (s 2(1) item 3)	—
Therapeutic Goods Amendment (2018 Measures No. 1) Regulations 2018	26 Nov 2018 (F2018L01612)	27 Nov 2018 (s 2(1) item 1)	—
Therapeutic Goods Amendment (Scheduling Advisory Committee Members) Regulations 2019	8 Feb 2019 (F2019L00109)	9 Feb 2019 (s 2(1) item 1)	—
Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2019	25 Mar 2019 (F2019L00396)	Sch 1 (items 4–26): 1 July 2019 (s 2(1) items 2, 3)	—
Therapeutic Goods Amendment (Fees for Relisted Medicine) Regulations 2019	25 Sept 2019 (F2019L01260)	26 Sept 2019 (s 2(1) item 1)	—
Therapeutic Goods Amendment (Approval of Advertisements) Regulations 2019	14 Nov 2019 (F2019L01465)	15 Nov 2019 (s 2(1) item 1)	—

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019	18 Dec 2019 (F2019L01660)	Sch 5, 7 and Sch 9 (items 1–10): 1 Jan 2020 (s 2(1) items 4, 6, 8) Sch 6: 1 Jan 2021 (s 2(1) item 5) Sch 8, Sch 9 (items 11–13) and Sch 10 (item 2): 19 Dec 2019 (s 2(1) items 7, 9, 10)	—
Therapeutic Goods Amendment (Radiopharmaceuticals and Radiopharmaceutical Active Ingredients) Regulations 2020	1 May 2020 (F2020L00544)	2 May 2020 (s 2(1) item 1)	—
Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2020	15 June 2020 (F2020L00720)	Sch 1 (items 2, 4–27): 1 July 2020 (s 2(1) item 1)	—
Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020	23 July 2020 (F2020L00946)	Sch 4, Sch 8 (items 24–31), Sch 9 and Sch 10 (item 2): 24 July 2020 (s 2(1) items 3, 7, 9) Sch 5 and 6: 23 July 2020 (s 2(1) items 4, 5)	—
Therapeutic Goods Legislation Amendment (2020 Measures No. 2) Regulations 2020	14 Dec 2020 (F2020L01598)	Sch 1 (items 3–10): 15 Dec 2020 (s 2(1) item 3)	—
Therapeutic Goods Legislation Amendment (2021 Measures No. 1) Regulations 2021	16 Apr 2021 (F2021L00450)	Sch 1 (items 1, 2): 19 Apr 2021 (s 2(1) item 2) Sch 1 (item 3): 17 Apr 2021 (s 2(1) item 3)	—
Therapeutic Goods Legislation Amendment (Fees) Regulations 2021	3 June 2021 (F2021L00688)	Sch 1 (items 2, 3): 1 July 2021 (s 2(1) item 1)	—
Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021	27 July 2021 (F2021L01032)	Sch 1 (items 1, 2, 6–8, 13, 15): 28 July 2021 (s 2(1) item 1)	—
Minamata Convention on Mercury (Consequential Amendments) Regulations 2021	5 Oct 2021 (F2021L01390)	Sch 1 (items 57–59): 7 Mar 2022 (s 2(1) item 1)	—
Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021	28 Oct 2021 (F2021L01474)	Sch 1 (items 54–61, 70–82, 87): 29 Oct 2021 (s 2(1) item 7)	—
Therapeutic Goods Legislation Amendment (2021 Measures No. 4) Regulations 2021	17 Dec 2021 (F2021L01809)	Sch 1 (items 5–10): 18 Dec 2021 (s 2(1) item 3) Sch 1 (items 11–18): 1 Jan 2022 (s 2(1) item 4)	—

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022	4 Mar 2022 (F2022L00243)	Sch 1 (items 3, 4): 31 Mar 2022 (s 2(1) item 2) Sch 2: 7 Mar 2022 (s 2(1) item 3) Sch 3 (item 4): 5 Mar 2022 (s 2(1) item 4)	—
Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2022	13 Apr 2022 (F2022L00600)	Sch 1 (items 5–11): 1 July 2022 (s 2(1) item 1)	—
Therapeutic Goods Legislation Amendment (2022 Measures No. 2) Regulations 2022	30 Sept 2022 (F2022L01300)	Sch 3: 1 Oct 2022 (s 2(1) item 3)	—
Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022	19 Dec 2022 (F2022L01687)	Sch 2: 20 Dec 2022 (s 2(1) item 1)	—
Therapeutic Goods Legislation Amendment (2023 Measures No. 1) Regulations 2023	13 June 2023 (F2023L00769)	Sch 1 (items 1–13): 21 June 2023 (s 2(1) item 2) Sch 1 (items 20–28, 30, 52, 54): 14 June 2023 (s 2(1) item 3)	—
Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2023	13 June 2023 (F2023L00770)	Sch 1 (7–13): 1 July 2023 (s 2(1) item 1)	—

Endnote 4—Amendment history

Provision affected	How affected
Part 1	
r 1	rs No 369, 1998
r 2	am No 485, 1991; No 332, 1992; No 364, 1994; No 111, 1995; No 208, 1995; No 328, 1995; No 398, 1997; No 399, 1997; No 400, 1997; No 369, 1998; No 62, 1999; No 324, 1999; No 29, 2000; No 48, 2000; No 358, 2000; No 159, 2001; No 234, 2002; No 111, 2003; No 151, 2003; No 301, 2003; No 361, 2003; No 127, 2004; No 374, 2009; No 26, 2010; No 30, 2011; No 102, 2011; No 251, 2012; No 75, 2015; No 214, 2015; F2016L00109; F2016L01614; F2017L00853; F2017L01561; F2018L00311; F2018L00865; F2018L01434; F2019L00396; F2022L01687
	ed C88
	am F2019L01465; F2019L01660; F2020L00720; F2020L00946 (amdt never applied (Sch 9 item 1)); F2021L01032; F2021L01390; F2022L01300; F2023L00769
r 2A	ad No 361, 2003
r 3	am No 89, 1992; No 430, 1992
	rs No 111, 1995
	am No 200, 1996
	rs No 361, 2003
	am No 26, 2010; No 102, 2011; No 281, 2011; No 87, 2015
	ed C88
	am F2021L01474
r 3AA	ad No 102, 2011
	am No 213, 2015; F2018L00311; F2018L01434
r 3A	ad 2003 No 301
	am 2005 No 192; F2017L00853
r 3B	ad F2018L00865
r 3C	ad F2023L00769
Part 2	
Division 1	
Division 1 heading	ad No 400, 1997
Division 1	rs No 301, 2003
r 4	am No 19, 1992; No 159, 2001
	rs No 301, 2003
r 4A	ad No 301, 2003
r 5	rep No 301, 2003
r 5A	ad No 19, 1992
	rep No 301, 2003
Division 2	ad No 400, 1997
	rep F2018L00311
r 5B	ad No 400, 1997

Endnote 4—Amendment history

Provision affected	How affected
	am No 227, 1998; No 369, 1998; No 62, 1999; No 48, 2000; No 159, 2001; No 234, 2002; No 301, 2003; F2019L01465
	rep F2018L00311
r 5BA	ad No 301, 2003
	rep F2018L00311
r 5C	ad No 400, 1997
	am No 159, 2001
	rep F2018L00311
r 5D	ad No 400, 1997
	rep No 62, 1999
r 5E	ad No 400, 1997
	rep No 62, 1999
r 5F	ad No 400, 1997
	am No 324, 1999
	rep F2018L00311
r 5G	ad No 400, 1997
	am No 324, 1999; No 48, 2000; No 301, 2003
	rep F2018L00311
r 5H	ad No 400, 1997
	rep F2018L00311
r 5J	ad No 400, 1997
	am No 48, 2000
	rep F2018L00311
r 5K	ad No 400, 1997
	rep F2018L00311
r 5L	ad No 400, 1997
	am No 62, 1999; No 48, 2000; F2018L00311
	rep F2018L00311
r 5M	ad No 400, 1997
	am F2016L00109; F2018L00311
	rep F2018L00311
r 5N	ad No 400, 1997
	am F2018L00311
	rep F2018L00311
r 5P	ad No 400, 1997
	rep F2018L00311
r 5Q	ad No 400, 1997
	am No 369, 1998; No 48, 2000; No 159, 2001; No 301, 2003; No 281, 2011; F2016L00109; F2018L00311; F2019L01465
	rep F2018L00311

Endnote 4—Amendment history

Provision affected	How affected
Division 3	
Division 3 heading	ad. 1997 No. 400
	rs. 2003 No. 301
Division 3	rs. 2003 No. 301
r. 5R	ad. 1997 No. 400
	rep. 2003 No. 301
r 6	am 1992 No. 19; 1995 No. 253; 1996 No. 9; 1998 No. 227; 2000 No. 48; 2001 No. 159; 2002 Nos. 9 and 234
	rs. 2003 No. 301
	rep F2018L00311
r 6AA	ad. 2000 No. 48
	rep. 2003 No. 301
	ad. 2009 No. 374
	am F2016L01614; F2018L00311
r 6AB	ad. 2000 No. 48
	rep. 2003 No. 301
r 6A	ad No 208, 1995
	rs No 301, 2003; No 192, 2005
	rep F2018L00311
r 6B	ad 2003 No 301
	am F2018L01434; F2021L01809
r 7	rs No 301, 2003
	am F2016L00109
	rs F2018L00311
	am F2021L01809; F2022L01687
r 7A	ad No 48, 2000
	rep No 301, 2003
	ad F2018L00311
r 7B	ad No 48, 2000
	rep No 301, 2003
r 7C	ad No 48, 2000
	rep No 301, 2003
r 7D	ad No 48, 2000
	rep No 301, 2003
r 7E	ad No 48, 2000
	rep No 301, 2003
r 7F	ad No 48, 2000
	rep No 301, 2003
r 7G	ad No 48, 2000
	rep No 301, 2003

Endnote 4—Amendment history

Provision affected	How affected
r 7H	ad No 48, 2000
	rep No 301, 2003
r. 7J	ad. 2000 No. 48
	rep. 2003 No. 301
Division 4	
Division 4 heading	ad. 1997 No. 400
	rs. 2003 No. 301
Division 4	rs. 2003 No. 301
r 8	am No 400, 1997
	rs No 301, 2003
	am No 122, 2006; F2018L00311; F2018L01434; F2021L01809
r 8A	ad No 301, 2003
	am No 122, 2006
	rep F2018L00311
Division 5	ad No 400, 1997
	rep No 48, 2000
	ad No 301, 2003
	rep F2018L00311
r 9	rs No 48, 2000; No 301, 2003
	rep F2018L00311
r. 9AA	ad. 1997 No. 400
	rs. 2000 No. 48
	am. 2002 No. 315
	rep. 2003 No. 301
rr. 9AB–9AE	ad. 1997 No. 400
	rep. 2000 No. 48
Part 2A	
Part 2A	ad. 1992 No. 430
r 9A	ad 1992 No 430
	am. 1994 No. 364; 1995 No. 208; 1998 No. 369; 1999 No. 62; 2002 Nos. 9 and 315; 2003 No. 257; F2019L01660; F2021L01474
r 9B	ad No 257, 2003
	am No 102, 2011; F2018L00311; F2019L01660
Part 2B	ad. 2000 No. 48
	rep. 2003 No. 301
r. 9P	ad. 2000 No. 48
	rep. 2003 No. 301
r. 9Q	ad. 2000 No. 48
	rep. 2003 No. 301
r. 9R	ad. 2000 No. 48

Endnote 4—Amendment history

Provision affected	How affected
	am. 2002 No. 9
	rep. 2003 No. 301
r. 9S	ad. 2000 No. 48
	am. 2002 No. 315
	rep. 2003 No. 301
Part 2C	
Part 2C	ad. 2002 No. 234
Division 2C.1	
r 10	rs No 234, 2002
	am No 213, 2015; F2018L00311
r 10AAA	ad F2017L00853
	am F2017L01561
r 10AAB	ad F2017L00853
	am F2017L01561; F2018L00865
r 10AAC	ad F2017L00853
	am F2017L01561
r 10AAD	ad F2017L01561
	am F2023L00769
r 10A (prev r 13)	rep F2016L00109
r 10AA	ad No 214, 2015
	am F2017L01561; F2018L00311; F2019L00396
r 10AB	ad F2016L00109
r 10AC	ad F2016L00109
r 10B (prev r 14)	rs No 30, 2011
r 10C (prev r 14A)	am F2020L00946
r. 10D	ad. 2002 No. 234
Division 2C.2	
r. 10E	ad. 2002 No. 234
r. 10F	ad. 2002 No. 234
	am. 2009 No. 140
	rs F2016L00109
r 10FA	ad F2016L00109
Division 2C.3	
Division 2C.3	ad. 2011 No. 30
r. 10G	ad. 2011 No. 30
r. 10H	ad. 2011 No. 30
	am. 2011 No. 281
	rs F2016L00109
r 10HA	ad F2016L00109
r. 10I	ad. 2011 No. 30

Endnote 4—Amendment history

Provision affected	How affected
r. 10J	ad. 2011 No. 30
Part 2CA	
Part 2CA	ad F2021L01390
Division 1	
r 10JA	ad F2021L01390
Division 2	
r 10JB	ad F2021L01390
Division 3	
r 10JC	ad F2021L01390
Division 4	
r 10JD	ad F2021L01390
r 10JE	ad F2021L01390
r 10JF	ad F2021L01390
Division 5	
r 10JG	ad F2021L01390
r 10JH	ad F2021L01390
Part 2D	
Part 2D	ad F2018L00311
r 10K	ad F2018L00311
r 10L	ad F2018L00311
	am F2021L01032
Part 2E	
Part 2E	ad F2020L00946
r 10M	ad F2020L00946
Part 3	
Part 3 heading	rs. 2011 No. 30
r 10A	ad No 252, 2001
	renum No 234, 2002
r 11 (prev r 10A)	am No 127, 2004; F2018L00311
r. 11	am. 1992 No. 89; 1994 No. 150
	rep. 2002 No. 234
r 11A	ad 1994 No 150
	rep 2002 No 234
	ad 2011 No 30
	am F2016L01614; F2023L00769
r. 12	am. 1991 No. 84; 1992 No. 89; 1995 No. 33; 1996 No. 9; 2000 No. 358; 2001 No. 343; 2002 Nos. 84, 234 and 345; 2003 No. 258; 2010 No. 26
	rs. 2011 No. 30
	am F2021L01032
r 12A	ad 1991 No 485

Endnote 4—Amendment history

Provision affected	How affected
	am 1999 No 62; 2000 No 358; 2002 Nos 9 and 234; 2011 No 30; F2016L01652 (Sch 1 item 1 disallowed); F2017L00853; F2017L01561; F2022L00243
r. 12AAA	ad. 2003 No. 111
	rep. 2010 No. 266
r. 12AAB	ad. 2003 No. 111
	am. 2011 No. 30
r. 12AA	ad. 2000 No. 358
	am. 2011 No. 30
r 12AB	ad No 358, 2000
	am No 258, 2003; No 361, 2003; No 30, 2011; F2016L0109; F2019L01660
r 12AC	ad No 358, 2000
	am No 361, 2003; F2019L01660; F2023L00769
r 12AD	ad No 358, 2000
	am No 234, 2002; No 30, 2011; F2019L01660
r 12B	ad 1991 No 485
	am No 19, 1992; No 62, 1999; No 358, 2000; No 258, 2003; No 361, 2003; No 30, 2011; F2017L00853; F2020L00946; F2020L01598; F2021L01474; F2021L01809; F2022L01687; F2023L00769
r 12C	ad 2002 No 234
	rep 2010 No 26
	ad 2011 No 30
	am F2017L00853
r 13	am No 19, 1992; No 9, 2002
	reloc and renum No 234, 2002
r 14	am No 9, 2002; No 234, 2002
	reloc and renum No 234, 2002
r 14A	ad No 430, 1992
	reloc and renum No 234, 2002
r 14B	ad 1992 No 430
	rep 2002 No 234
r 14C	ad 1992 No 430
	rep 2002 No 234
r 15	am No 19, 1992; No 398, 1997; No 62, 1999; No 102, 2011; F2018L00311; F2020L00946
r 15AA	ad F2021L00450
r 15A	ad 2003 No 258
	am 2010 No 26; 2011 No 102
	rs 2012 No 251
	am F2017L00853
r 16	am No 89, 1992; No 26, 2010
	rep F2020L00946
r. 16AA	ad. 2003 No. 151

Endnote 4—Amendment history

Provision affected	How affected
	rs No 75, 2015
r 16AB	ad No 30, 2011
	am F2018L00865; F2018L01434
Part 3A	
Part 3A heading	am. 1999 No. 62
	rs. 2000 No. 29
Part 3A	ad. 1992 No. 19
Division 1	
Division 1 heading	ad. 2000 No. 29
	rs F2017L01561
r. 16A	ad. 1992 No. 19
	am. 2011 No. 281
Division 1A	
Division 1A heading	ad F2017L01561
r. 16B	ad. 1992 No. 19
	rep F2017L01561
r. 16C	ad. 1992 No. 19
	am. 1992 No. 109; 1998 No. 227; 1999 No. 62; F2016L00109
	rs F2017L01561
	am F2018L00311
r. 16D	ad. 1992 No. 19
	am. 1992 No. 109; 1998 No. 227; 1999 No. 62; 2003 No. 151
	rs F2017L01561
r 16DA	ad F2017L01561
	am F2018L00865
r. 16E	ad. 1992 No. 19
	am F2017L01561
r. 16F	ad. 1992 No. 19
	am. 1998 No. 227; 1999 No. 62; 2003 No. 151; F2017L01561
r. 16G	ad. 1992 No. 109
	am. 1998 No. 227; 1999 No. 62; F2017L01561
Division 2	
Division 2	ad. 2000 No. 29
r 16GA	ad No 29, 2000
	am No 151, 2003; F2018L00311
Division 3	
Division 3	ad. 2011 No. 30
r 16GB	ad No 30, 2011
	am No 281, 2011
	rep F2018L00311

Endnote 4—Amendment history

Provision affected	How affected
r 16GC	ad No 30, 2011
	am No 281, 2011
	rs F2018L00311
r 16GD	ad No 30, 2011
	am No 281, 2011
	rs F2018L00311
r 16GE	ad No 30, 2011
	am F2018L00311
r 16GF	ad No 30, 2011
	am F2018L00311
Division 4	
Division 4 heading	am F2018L01434
Division 4	ad F2018L00311
r 16GG	ad F2018L00311
	am F2019L00396
r 16GH	ad F2018L00311
	am F2018L01434; F2019L00396
r 16GI	ad F2018L00311
	am F2020L00946
r 16GIA	ad F2021L00450
r 16GJ	ad F2018L00311
	am F2018L01434
Part 3B	
Part 3B	ad 1997 No 399
	rs F2017L00853
r 16H	ad 1997 No 399
	am 1999 No 62
	rs F2017L00853
r 16I	ad 1997 No 399
	am 1999 No 62
	rep F2017L00853
r 16J	ad 1997 No 399
	am 1999 No 62; F2016L00109
	rs F2017L00853
	am F2018L00311
r 16K	ad F2017L00853
r 16L	ad F2017L00853
r 16M	ad F2017L00853
	am F2019L01660

Endnote 4—Amendment history

Provision affected	How affected
Part 3C	
Part 3C	ad F2017L00853
r 16P	ad F2017L00853
r 16Q	ad F2017L00853
r 16R	ad F2017L00853
	am F2018L00311
r 16S	ad F2017L00853
	am F2018L00311
r 16T	ad F2017L00853
	am F2018L00311
Part 3D	
Part 3D	ad F2022L01300
r 16U	ad F2022L01300
r 16V	ad F2022L01300
	am F2023L00769
r 16W	ad F2022L01300
r 16X	ad F2022L01300
r 16Y	ad F2022L01300
Part 4	
r. 17	am. 1994 No. 150; 2002 No. 234
r. 18	am. 2002 No. 234
r. 22	am. 1992 Nos. 19 and 89
Part 5	
r 23	am No 150, 1994; No 252, 2001; No 234, 2002; No 361, 2003; F2018L00311; F2019L01660
r 24	am. 1991 No. 84; 2002 No. 234; 2004 No. 78
r 25	am No 150, 1994; No 252, 2001; No 234, 2002; F2016L00109; F2018L00311; F2019L01660
r 26	am No 150, 1994; No 252, 2001; F2019L01660
r 26A	ad No 252, 2001
	am No 234, 2002; F2018L00311; F2019L01660
r 27	rs. 1994 No. 150
	am. 2002 No. 234; F2019L01660
r 28	am No 234, 2002; F2019L01660
r 29	am No 150, 1994; No 364, 1994; No 252, 2001; No 234, 2002; F2019L01660
r 30	am No 234, 2002; No 361, 2003; F2019L01660
r 31	am No 252, 2001; No 234, 2002; F2018L00311
r. 32	am. 1994 No. 150; 2002 No. 9
r. 33	am. 2002 No. 9

Endnote 4—Amendment history

Provision affected	How affected
Part 5A	
Part 5A	ad. 2011 No. 30
r. 33A	ad. 2011 No. 30
r. 33B	ad. 2011 No. 30
r. 33C	ad. 2011 No. 30
Part 6	
Division 1	
Division 1 heading	ad. 1997 No. 400
	rs. 2002 No. 234; 2009 No. 374
	rep F2016L01614
Division 1	rs. 2009 No. 374
	rep F2016L01614
r. 34	am. 1995 No. 208; 1999 No. 62; 2002 No. 234
	rs. 2009 No. 374
	rep F2016L01614
r. 34A	ad. 2009 No. 374
	am. 2011 No. 30; 2012 No. 251; No. 220, 2013
	rep F2016L01614
r. 34B	ad. 2009 No. 374
	rep F2016L01614
Division 1A	
Division 1A heading	rs F2016L01614
Division 1A	ad. 2009 No. 374
r 35	am. 1991 No. 485; 1999 No. 62
	rs 2002 No 234; 2009 No 374; F2016L01614
r 35A	ad 2009 No 374
	am 2012 No 251; No 220, 2013; F2016L01614
r 35B	ad 2009 No 374
	am 2011 No 102; F2016L01614
Division 1B	
Division 1B	ad 2009 No 374
	rep F2016L01614
r. 36	am. 1991 No. 485; 1999 No. 62; 2002 No. 234
	rs. 2009 No. 374
	rep F2016L01614
r. 36A	ad. 2009 No. 374
	am. 2012 No. 251; No. 220, 2013
	rep F2016L01614
r. 36B	ad. 2009 No. 374
	am. 2011 No. 102

Endnote 4—Amendment history

Provision affected	How affected
	rep F2016L01614
Division 1C	
Division 1C	ad 2009 No 374
	rep F2016L01614
r. 37	am. 1997 No. 400
	rs. 2009 No. 374
	rep F2016L01614
r. 37A	ad. 2009 No. 374
	am. 2012 No. 251; No. 220, 2013
	rep F2016L01614
r. 37B	ad. 2009 No. 374
	am. 2011 No. 102; No. 220, 2013
	rep F2016L01614
Division 1D	
Division 1D	ad. 2009 No. 374
r. 38	am. 1991 No. 485; 1997 No. 400; 2002 No. 234; 2009 No. 63
	rs. 2009 No. 374
r 38A	ad 2009 No 374
	am 2012 No 251; F2016L01614
r 38B	ad 2009 No 374
	am 2011 Nos 102 and 281; No 220, 2013; F2016L01614
Division 1DA	
Division 1DA	ad 2011 No 281
	rep F2016L01614
r. 38C	ad. 2011 No. 281
	rep F2016L01614
r. 38D	ad. 2011 No. 281
	am. 2012 No. 251; No. 220, 2013
	rep F2016L01614
r. 38E	ad. 2011 No. 281
	am No. 220, 2013
	rep F2016L01614
r. 39	am. 1997 No. 400
	rep. 2009 No. 374
Division 1E	
Division 1E	ad. 2009 No. 374
r. 39	ad. 2009 No. 374
r 39A	ad 2009 No 374
	am 2012 No 251; No 220, 2013; F2016L01614
r 39B	ad 2009 No 374

Endnote 4—Amendment history

Provision affected	How affected
	am 2011 No 102; F2016L01614
Division 1EA	
Division 1EA	ad. 2011 No. 30
r. 39C	ad. 2011 No. 30
r 39D	ad 2011 No 30
	am 2012 No 251; No 220, 2013; F2016L01614
r 39E	ad 2011 No 30
	am F2016L01614
Division 1EB	
Division 1EB heading	rs F2016L01614
Division 1EB	ad 2012 No 251
r 39F	ad 2012 No 251
	rs F2016L01614
r 39G	ad 2012 No 251
	am No 220, 2013; F2016L01614
r 39H	ad 2012 No 251
	am No 220, 2013; F2016L01614
Division 1F	
Division 1F	ad. 2009 No. 374
r 40	am 1997 No 400
	rs 2009 No 374
	am 2009 No 374; 2011 Nos 30 and 281; 2012 No 251; F2016L01614
r. 41	am. 1991 No. 485; 1997 No. 400; 2002 No. 234
	rs. 2009 No. 374
r. 41A	ad. 2009 No. 374
r. 41B	ad. 2009 No. 374
r. 41C	ad. 2009 No. 374
	am. 2011 No. 102
r. 41D	ad. 2009 No. 374
r. 41E	ad. 2009 No. 374
r. 41F	ad. 2009 No. 374
r. 41G	ad. 2009 No. 374
r. 41H	ad. 2009 No. 374
r. 41I	ad. 2009 No. 374
r. 41J	ad. 2009 No. 374
r. 42	am. 1997 No. 400
	rs. 2009 No. 374
	am. 2011 No. 102; 2012 No. 251; F2016L00109
Division 2	ad No 400, 1997
	rep F2018L00311

Endnote 4—Amendment history

Provision affected	How affected
r 42A	ad No 400, 1997
	rep F2018L00311
r 42B	ad No 400, 1997
	am No 159, 2001; No 301, 2003
	rep F2018L00311
r 42C	ad No 400, 1997
	am No 369, 1998; No 234, 2002; No 111, 2003; No 258, 2003; No 122, 2006; No 102, 2011
	rep F2018L00311
r 42D	ad No 400, 1997
	am No 361, 2003
	rep F2018L00311
r 42E	ad No 400, 1997
	am No 369, 1998; No 234, 2002; No 111, 2003
	rep F2018L00311
r 42F	ad No 400, 1997
	rep F2018L00311
r 42G	ad No 400, 1997
	rep F2018L00311
r 42H	ad No 400, 1997
	am No 48, 2000
	rep F2018L00311
r 42J	ad No 400, 1997
	am No 48, 2000; No 159, 2001; No 315, 2002; No 258, 2003; No 361, 2003; No 122, 2006; No 63, 2009
	rep F2018L00311
r 42K	ad No 400, 1997
	am No 369, 1998; No 234, 2002; No 111, 2003
	rep F2018L00311
r 42L	ad No 400, 1997
	rep F2018L00311
r 42M	ad No 400, 1997
	rep F2018L00311
r 42N	ad No 400, 1997
	am No 102, 2011
	rep F2018L00311
r 42P	ad No 400, 1997
	rep F2018L00311
r 42Q	ad No 400, 1997
	rep F2018L00311
Division 3 heading	rs No 48, 2000

Endnote 4—Amendment history

Provision affected	How affected
	rep F2018L00311
Division 3	ad No 400, 1997
	rep F2018L00311
Subdivision 1 heading	ad No 48, 2000
	rep F2018L00311
r 42R	ad No 400, 1997
	rep F2018L00311
r 42S	ad No 400, 1997
	am No 48, 2000
	rep F2018L00311
r 42T	ad No 400, 1997
	am No 369, 1998; No 48, 2000; No 234, 2002; No 102, 2011
	rep F2018L00311
r 42U	ad No 400, 1997
	am No 361, 2003
	rep F2018L00311
r 42V	ad No 400, 1997
	rep F2018L00311
r 42W	ad No 400, 1997
	am No 48, 2000
	rep F2018L00311
r 42X	ad No 400, 1997
	am No 258, 2003
	rep F2018L00311
r 42Y	ad No 400, 1997
	am No 369, 1998; No 48, 2000; No 234, 2002; No 315, 2002; No 111, 2003; No 102, 2011
	rs No 301, 2003
	rep F2018L00311
r 42Z	ad No 400, 1997
	rep F2018L00311
r 42ZA	ad No 400, 1997
	rep F2018L00311
r 42ZB	ad No 400, 1997
	am No 102, 2011
	rep F2018L00311
r 42ZC	ad No 400, 1997
	rs No 48, 2000
	rep F2018L00311
Subdivision 2	ad No 48, 2000
	rep F2018L00311

Endnote 4—Amendment history

Provision affected	How affected
r 42ZCAA	ad No 48, 2000
	am No 159, 2001; No 142, 2012
	rep F2018L00311
r 42ZCAB	ad No 48, 2000
	am No 159, 2001; No 234, 2002; No 301, 2003; No 159, 2004
	rep F2018L00311
r 42ZCAC	ad No 48, 2000
	rep F2018L00311
r 42ZCAD	ad No 48, 2000
	am No 315, 2002; No 111, 2003
	rep F2018L00311
r 42ZCAE	ad No 48, 2000
	rep F2018L00311
r 42ZCAF	ad No 48, 2000
	rep F2018L00311
r 42ZCAG	ad No 48, 2000
	rep F2018L00311
r 42ZCAGA	ad No 122, 2006
	rep F2018L00311
r 42ZCAH	ad No 48, 2000
	rep F2018L00311
r 42ZCAI	ad No 48, 2000
	am No 234, 2002; No 315, 2002; No 301, 2003; No 122, 2006; No 102, 2011
	rep F2018L00311
r 42ZCAJ	ad No 48, 2000
	am No 142, 2012
	rep F2018L00311
r 42ZCAK	ad No 48, 2000
	rep F2018L00311
r 42ZCAL	ad No 315, 2002
	rep F2018L00311
Division 3A	
Division 3A	ad. 1999 No. 209
	rs. 2010 No. 129
Subdivision 3A.1	
Subdivision 1 renumbered Subdivision 3A.1	2010 No. 129
r. 42ZCA	ad. 1999 No. 209
	rs. 2010 No. 129

Endnote 4—Amendment history

Provision affected	How affected
Subdivision 3A.2	
Subdivision 2	2010 No. 129
renumbered Subdivision 3A.2	
r. 42ZCB	ad. 1999 No. 209
	rs. 2010 No. 129
r 42ZCC	ad No 209, 1999
	rs No 129, 2010
	am F2019L00109
r. 42ZCD	ad. 1999 No. 209
	rs. 2010 No. 129
r. 42ZCE	ad. 1999 No. 209
	rs. 2010 No. 129
r. 42ZCF	ad. 1999 No. 209
	rs. 2010 No. 129
r. 42ZCG	ad. 1999 No. 209
	rs. 2010 No. 129
r. 42ZCH	ad. 1999 No. 209
	rs. 2010 No. 129
r. 42ZCI	ad. 1999 No. 209
	rs. 2010 No. 129
r. 42ZCJ	ad. 1999 No. 209
	rs. 2010 No. 129
Subdivision 3A.3	
Subdivision 3	2010 No. 129
renumbered Subdivision 3A.3	
r. 42ZCK	ad. 1999 No. 209
	rs. 2010 No. 129
r. 42ZCL	ad. 1999 No. 209
	rs. 2010 No. 129
r. 42ZCM	ad. 1999 No. 209
	rs. 2010 No. 129
r 42ZCN	ad No 209, 1999
	rs No 129, 2010
	am F2019L00109
r. 42ZCO	ad. 1999 No. 209
	rs. 2010 No. 129
r. 42ZCP	ad. 1999 No. 209
	rs. 2010 No. 129
Division 3B	
Division 3B	ad. 2010 No. 129

Endnote 4—Amendment history

Provision affected	How affected
Subdivision 3B.1	
r. 42ZCQ	ad. 1999 No. 209
	rs. 2010 No. 129
Subdivision 3B.2	
r. 42ZCR	ad. 1999 No. 209
	rs. 2010 No. 129
r 42ZCS	ad No 209, 1999
	rs No 129, 2010
	am F2019L00109
r. 42ZCT	ad. 1999 No. 209
	rs. 2010 No. 129
r. 42ZCU	ad. 1999 No. 209
	rs. 2010 No. 129
r. 42ZCV	ad. 1999 No. 209
	rs. 2010 No. 129
r. 42ZCW	ad. 1999 No. 209
	rs. 2010 No. 129
r. 42ZCX	ad. 1999 No. 209
	rs. 2010 No. 129
r. 42ZCY	ad. 1999 No. 209
	rs. 2010 No. 129
r. 42ZCZ	ad. 1999 No. 209
	rs. 2010 No. 129
Subdivision 3B.3	
r. 42ZCZA	ad. 1999 No. 209
	rs. 2010 No. 129
r. 42ZCZB	ad. 1999 No. 209
	rs. 2010 No. 129
r. 42ZCZC	ad. 2010 No. 129
r 42ZCZD	ad No 129, 2010
	am F2019L00109
r. 42ZCZE	ad. 2010 No. 129
r. 42ZCZF	ad. 2010 No. 129
Division 3C	
Division 3C	ad. 2010 No. 129
r. 42ZCZG	ad. 2010 No. 129
r. 42ZCZH	ad. 2010 No. 129
Division 3D	
Division 3D	ad. 2010 No. 129

Endnote 4—Amendment history

Provision affected	How affected
Subdivision 3D.1	
r. 42ZCZI	ad. 2010 No. 129
	am F2017L01561
Subdivision 3D.2	
r. 42ZCZJ	ad. 2010 No. 129
r. 42ZCZK	ad. 2010 No. 129
r. 42ZCZL	ad. 2010 No. 129
r. 42ZCZM	ad. 2010 No. 129
r. 42ZCZN	ad. 2010 No. 129
r. 42ZCZO	ad. 2010 No. 129
r. 42ZCZP	ad. 2010 No. 129
	am F2017L01561
r. 42ZCZQ	ad. 2010 No. 129
r. 42ZCZR	ad. 2010 No. 129
r. 42ZCZS	ad. 2010 No. 129
Subdivision 3D.3	
r. 42ZCZT	ad. 2010 No. 129
r. 42ZCZU	ad. 2010 No. 129
r. 42ZCZV	ad. 2010 No. 129
r. 42ZCZW	ad. 2010 No. 129
r. 42ZCZX	ad. 2010 No. 129
Division 4	ad. 1999 No. 62
	rep. 2009 No. 374
r. 42ZD	ad. 1999 No. 62
	rep. 2009 No. 374
r. 42ZE	ad. 1999 No. 62
	am. 2000 No. 29
	rep. 2009 No. 374
r. 42ZF	ad. 1999 No. 62
	am. 2000 No. 29
	rep. 2009 No. 374
r. 42ZG	ad. 1999 No. 62
	rep. 2009 No. 374
r. 42ZH	ad. 1999 No. 62
	rep. 2009 No. 374
r. 42ZI	ad. 1999 No. 62
	rep. 2009 No. 374
r. 42ZJ	ad. 1999 No. 62
	rep. 2009 No. 374
r. 42ZK	ad. 1999 No. 62

Endnote 4—Amendment history

Provision affected	How affected
	rep. 2009 No. 374
r. 42ZL	ad. 1999 No. 62
	rep. 2009 No. 374
r. 42ZM	ad. 1999 No. 62
	rep. 2009 No. 374
r. 42ZN	ad. 1999 No. 62
	am. 2000 No. 29
	rep. 2009 No. 374
r. 42ZO	ad. 1999 No. 62
	rep. 2009 No. 374
r. 42ZP	ad. 1999 No. 62
	rep. 2009 No. 374
r. 42ZQ	ad. 1999 No. 62
	am. 2000 No. 29
	rep. 2009 No. 374
r. 42ZR	ad. 1999 No. 62
	rep. 2009 No. 374
r. 42ZS	ad. 1999 No. 62
	rep. 2009 No. 374
r. 42ZT	ad. 1999 No. 62
	rep. 2009 No. 374
r. 42ZU	ad. 1999 No. 62
	rep. 2009 No. 374
r. 42ZV	ad. 1999 No. 62
	rep. 2009 No. 374
r. 42ZW	ad. 1999 No. 62
	rep. 2009 No. 374
r. 42ZX	ad. 1999 No. 62
	am. 2000 No. 29
	rep. 2009 No. 374
r. 42ZY	ad. 1999 No. 62
	rep. 2009 No. 374
r. 42ZZ	ad. 1999 No. 62
	rep. 2009 No. 374
Division 5	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZA	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZB	ad. 2000 No. 29
	rep. 2009 No. 374

Endnote 4—Amendment history

Provision affected	How affected
r. 42ZZC	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZD	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZE	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZF	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZG	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZH	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZI	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZJ	ad. 2000 No. 29
	am. 2003 No. 258
	rep. 2009 No. 374
r. 42ZZK	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZL	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZM	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZN	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZO	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZP	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZQ	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZR	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZS	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZT	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZU	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZV	ad. 2000 No. 29

Endnote 4—Amendment history

Provision affected	How affected
	rep. 2009 No. 374
r. 42ZZW	ad. 2000 No. 29
	rep. 2009 No. 374
r. 42ZZX	ad. 2000 No. 29
	rep. 2009 No. 374
Part 7	
Part 7 heading	rs. 1991 No. 84; 2009 No. 141
Division 1	
Division 1	ad. 2009 No. 141
Subdivision 1	
Subdivision 1 heading	rs. 2011 No. 30
r. 43AAA	ad. 2009 No. 141
	am. 2011 No. 281
	rs No 75, 2015
Subdivision 2	
Subdivision 2 heading	rs F2016L00109
r 43AAAA	ad F2016L00109
r. 43AAB	ad. 2009 No. 141
	rs. 2011 No. 30
	rs No 75, 2015
	am F2016L00109
r 43AABA	ad No 75, 2015
	rs F2016L00109
r 43AABB	ad No 75, 2015
r. 43AAC	ad. 2009 No. 141
	am. 2011 No. 30
	rs No 75, 2015
	am F2016L00109
r. 43AAD	ad. 2009 No. 141
	rs No 75, 2015
r. 43AAE	ad. 2009 No. 141
	am. 2011 No. 30; 2012 No. 142
	rs No 75, 2015
	am F2016L00109
r. 43AAF	ad. 2009 No. 141
	am. 2012 No. 142
	rs No 75, 2015
r. 43AAG	ad. 2009 No. 141
	am. 2011 No. 30
	rs No 75, 2015

Endnote 4—Amendment history

Provision affected	How affected
Subdivision 2A	
Subdivision 2A	ad F2016L00109
r 43AAGA	ad F2016L00109
r 43AAGB	ad F2016L00109
r 43AAGC	ad F2016L00109
r 43AAGD	ad F2016L00109
r 43AAGE	ad F2016L00109
r 43AAGF	ad F2016L00109
Subdivision 2B	
Subdivision 2B heading	ad F2016L00109
r 43AAGG	ad F2016L00109
	am F2021L00450
r. 43AAH	ad. 2009 No. 141
	rs No 75, 2015
r. 43AAI	ad. 2009 No. 141
Subdivision 3	
r 43AAJ	ad 2009 No 141
	am 2010 No 130; 2011 No 102; 2012 No 143; No 94, 2013; No 62, 2014; No 87, 2015; F2016L00667; F2017L00552; F2018L00759; F2019L00396; F2020L00720; F2021L00688; F2022L00600; F2023L00770
Division 2	
Division 2 heading	ad. 2009 No. 141
r 43	am No 151, 2003; No 30, 2011; No 214, 2015; F2018L00311
r 43A	ad No 222, 1994
	am No 234, 2002; No 102, 2011; No 214, 2015; F2018L00311; F2018L01612; F2019L01260
r. 43AA	ad. 1992 No. 19
	rs. 2011 No. 102
	am No 214, 2015
r. 43AB	ad. 2000 No. 267
	am No 214, 2015
r 43AC	ad No 214, 2015
	am F2017L00552; F2018L00759; F2019L00396; F2020L00720; F2021L00688; F2022L00600; F2023L00770
r 43ACA	ad F2018L00311
	am F2018L00759; F2019L00396; F2020L00720; F2021L00688; F2022L00600; F2023L00770
r 43AD	ad F2017L00853
r 43AE	ad F2018L00311
r 43AF	am F2019L00396
r 44AF	ad F2018L00311

Endnote 4—Amendment history

Provision affected	How affected
r 45	am No 84, 1991; No 485, 1991; No 222, 1994; No 364, 1994; No 192, 1995; No 131, 1996; No 162, 1997; No 398, 1997; No 399, 1997; No 247, 1998; No 62, 1999; No 123, 2000; No 267, 2000; No 143, 2002; No 151, 2003; No 361, 2003; No 159, 2004; No 192, 2005; No 212, 2006; No 161, 2007; No 117, 2008; No 179, 2009; No 130, 2010; No 30, 2011; No 102, 2011; No 143, 2012; No 94, 2013; No 62, 2014; No 87, 2015; No 214, 2015; F2016L00667; F2017L00552; F2017L00853; F2018L00311; F2018L00759; F2018L01612; F2019L00396; F2019L01660; F2020L00720; F2020L01598; F2021L00688; F2022L00600; F2023L00770
r 45AA	ad 1995 No. 192
	am 2002 No. 234; 2011 No. 30; No 214, 2015; F2018L01434; F2020L00720
r. 45A	ad. 1991 No. 84
	am. 1997 No. 162; 2000 No. 267; 2001 No. 160; 2002 No. 234; 2003 No. 151; 2004 No. 159; 2005 No. 192; 2006 No. 212; 2007 No. 161; 2008 No. 117
	rs. 2009 No. 141
	am No 179, 2009; No. 130, 2010; 2012 No. 143; No. 94, 2013; No 62, 2014
	rep No 75, 2015
Part 7A	ad No 228, 2009
	rep F2018L00311
r 45B	ad No 228, 2009
	rep F2018L00311
Part 8	
r 46A	ad 1992 No 332
	rs 2009 No 140
	am No 26, 2010; F2016L00109; F2016L01614; F2017L00853; F2017L01561; F2023L00769
r. 46	am. 1991 No. 84; 1992 No. 332; 1997 No. 399; 1999 No. 62; 2002 No. 234; 2011 Nos. 30 and 102
r 47	rs No 485, 1991
	am No 332, 1992; No 400, 1997; No 48, 2000; No 343, 2001; No 345, 2002; No 78, 2004; No 228, 2009; F2016L00109; F2018L00311
r. 47A	ad. 1991 No. 485
	am. 2011 No. 30
r. 47AA	ad. 2000 No. 358
	rep. 2003 No. 361
	rs. 2002 No. 234; 2011 No. 30
r 47B	ad 1991 No 485
	am 1999 No 62
	rs 2000 No 358
	am 2002 No 234; 2011 No 30; F2016L00109; F2017L00853
r 48	am No 84, 1991; No 332, 1992; No 430, 1992; No 192, 1995; No 399, 1997; No 48, 2000; No 234, 2002; No 301, 2003; No 30, 2011; No 75, 2015; F2016L00109; F2017L00853; F2018L00311; F2020L00946; F2022L00243; F2022L01300; F2023L00769

Endnote 4—Amendment history

Provision affected	How affected
Part 9	
Part 9	ad. 2012 No. 251
Division 1	
Division 1	ad No 63, 2014
r 48A	ad No 63, 2014
r 48B	ad No 63, 2014
Division 2	
Division 2 heading	ad No 63, 2014
r. 49	ad. 2012 No. 251
	am No 63, 2014
Division 3	
Division 3	ad No 214, 2015
r 50	ad No 214, 2015
Division 4	
Division 4	ad F2016L00109
r 51	ad F2016L00109
Division 5	
Division 5	ad F2017L00853
r 52	ad F2017L00853
r 53	ad F2017L00853
r 54	ad F2017L00853
r 55	ad F2017L00853
r 56	ad F2017L00853
Division 6	
Division 6	ad F2017L01561
r 57	ad F2017L01561
r 58	ad F2017L01561
r 59	ad F2017L01561
Division 7	
Division 7	ad F2018L00311
r 60	ad F2018L00311
r 61	ad F2018L00311
r 62	ad F2018L00311
Division 8	
Division 8	ad F2018L00516
r 63	ad F2018L00516
Division 9	
Division 9	ad F2018L00865
r 64	ad F2018L00865
	am F2018L01434

Endnote 4—Amendment history

Provision affected	How affected
r 65	ad F2018L00865
	ed C83
r 66	ad F2018L00865
Division 10	
Division 10	ad F2018L01434
r 67	ad F2018L01434
Division 11	
Division 11	ad F2019L01260
r 68	ad F2019L01260
Division 12	
Division 12	ad F2019L01660
Subdivision A	
r 69	ad F2019L01660
Subdivision B	
r 70	ad F2019L01660
	am F2020L00946
r 71	ad F2019L01660
	am F2020L00946
Subdivision C	
r 72	ad F2019L01660
	am F2021L01474
Subdivision D	
r 73	ad F2019L01660
Subdivision E	
r 74	ad F2019L01660
Subdivision F	
r 75	ad F2019L01660
Division 13	
Division 13	ad F2020L00946
r 76	ad F2020L00946
r 77	ad F2020L00946
Division 14	
Division 14	ad F2021L01032
r 78	ad F2021L01032
Division 15	
Division 15	ad F2021L01390
r 79	ad F2021L01390
Division 16	
Division 16	ad F2021L01474
r 80	ad F2021L01474

Endnote 4—Amendment history

Provision affected	How affected
r 81	ad F2021L01474
r 82	ad F2021L01474
r 83	ad F2021L01474
Division 17	
Division 17	ad F2021L01809
r 84	ad F2021L01809
r 85	ad F2021L01809
Division 18	
Division 18	ad F2022L00243
r 86	ad F2022L00243
Division 19	
Division 19	ad F2022L00243
r 87	ad F2022L00243
Division 20	
Division 20	ad F2022L01687
r 88	ad F2022L01687
r 89	ad F2022L01687
Division 21	
Division 21	ad F2023L00769
r 90	ad F2023L00769
Schedule 1	
Schedule 1	am 1992 No 89; 1992 No 332; 1994 No 150; 1994 No 364; 1995 No 208; 1997 No 398; 1999 No 324; 2001 No 159; 2003 No 258; 2006 No 122; 2012 No 142
Schedule 2	
Schedule 2 heading	rs 2003 No 301
Schedule 2	am 1994 No 150; 1995 No 208; 1997 No 398; 1999 No 324; 2000 No 48; 2001 No 159; 2001 No 252; 2002 No 234; 2006 No 122; F2016L01614; F2018L01434; F2021L01809
Schedule 3	
Schedule 3 heading	rs F2018L00311
Schedule 3	am 1991 No 84; 1991 No 485; 1992 No 19; 1992 No 89; 1992 No 370; 1994 No 150; 1994 No 364; 1995 No 208; 1997 No 398; 1997 No 399; 1999 No 62; 2002 No 84; 2002 No 114; 2002 No 143; 2002 No 234; 2002 No 315; 2004 No 78; 2010 No 26; No 213, 2015; F2018L01434; F2020L00946
Schedule 4	
Schedule 4 heading	am 1998 No 227 rs 2002 No 234
Schedule 4	am No 84, 1991; No 19, 1992; No 89, 1992; No 150, 1994; No 208, 1995; No 320, 1995; No 9, 1996; No 208, 1996; No 398, 1997; No 227, 1998; No 369, 1998; No 62, 1999; No 324, 1999; No 48, 2000; No 159, 2001; No 252, 2001; No 84, 2002; No 114, 2002; No 234, 2002; No 315, 2002; No 258, 2003; No 361, 2003; No 78, 2004; No 127, 2004; No 26, 2010; No 30, 2011; No 281, 2011; No 251, 2012; No 213, 2015; F2018L00311; F2018L00865; F2018L01434; F2019L00396; F2020L00946; F2020L01598

Endnote 4—Amendment history

Provision affected	How affected
Schedule 5	
Schedule 5 heading	am. 2002 No. 234
	rs. 2011 No. 30
Schedule 5	am. 1991 Nos. 84 and 485; 1992 Nos. 19, 89, 332 and 370; 1994 No. 150; 1995 No. 208; 1996 No. 9; 1997 Nos. 398 and 399; 1999 No. 62; 2000 Nos. 48 and 124; 2001 No. 159; 2002 No. 84; 2003 No. 258; 2010 No. 26; 2011 No. 30; 2012 No. 251; F2016L01652 (Sch 1 item 4 disallowed)
	ed C76
	am F2017L01561; F2018L00865; F2018L01434; F2018L01612
	ed C85
	am F2019L01660; F2021L01032; F2021L01474; F2022L00243; F2022L01687
Schedule 5A	
Schedule 5A heading	am No 234, 2002
	rs No 30, 2011; No 251, 2012
Schedule 5A	ad No 84, 1991
	am No 89, 1992; No 150, 1994; No 364, 1994; No 33, 1995; No 208, 1995; No 9, 1996; No 399, 1997; No 62, 1999; No 358, 2000; No 159, 2001; No 343, 2001; No 84, 2002; No 345, 2002; No 111, 2003; No 78, 2004; No 26, 2010; No 30, 2011; No 214, 2015; F2016L01652; F2017L00853; F2017L01561; F2018L00311; F2018L00516; F2018L00865; F2019L01660; F2020L00720; F2020L00946; F2021L01474; F2021L01809; F2023L00769
Schedule 5B	
Schedule 5B heading	rs. 2011 No. 30
Schedule 5B	ad 2003 No 111
	am 2010 No 266; 2011 No 30; F2017L00853
Schedule 6	
Schedule 6	am No 19, 1992; No 89, 1992; No 370, 1992; No 150; 1994; No 208, 1995; No 398, 1997; No 324, 1999; No 26, 2010
	rep F2020L00946
Schedule 7	
Schedule 7 heading	am No 234, 2002
Schedule 7	am No 84, 1991; No 19, 1992; No 89, 1992; No 370, 1992; No 150, 1994; No 208, 1995; No 398, 1997; No 227, 1998; No 324, 1999; No 124, 2000; No 159, 2001; No 26, 2010; No 251, 2012; F2018L00865; F2019L01660; F2020L00544; F2020L00946
Schedule 8	
Schedule 8 heading	am. 2002 No. 234
Schedule 8	am No 89, 1992; No 150, 1994; No 398, 1997; No 62, 1999; No 30, 2011; F2016L01652; F2017L01561; F2018L00865; F2020L00946
Schedule 9	
Schedule 9 heading	rs 2011 No 30

Endnote 4—Amendment history

Provision affected	How affected
Schedule 9	am 1991 Nos 84 and 485; 1992 Nos 19 and 89; 1993 No 141; 1994 Nos 150, 222 and 364; 1995 Nos 192 and 208; 1996 No 131; 1997 Nos 162, 398 and 400; 1998 No 247; 1999 Nos 62 and 324; 2000 Nos 29, 70, 123 and 267; 2001 No 160; 2002 Nos 143 and 234; 2003 No 151; 2004 No 159; 2005 No 192; 2006 No 212; 2007 No 161; 2008 No 117; 2009 Nos 141 and 179; 2010 Nos 26 and 130; 2011 Nos 102 and 281; 2012 Nos 143 and 251; No 94, 2013; No 62, 2014; No 75, 2015; No 87, 2015; No 213, 2015; No 214, 2015; F2016L00109; F2016L00667; F2016L01614; F2017L00552; F2017L00853
	ed C77
	am F2017L01561; F2018L00311; F2018L00759; F2018L00865; F2018L01434; F2018L01612; F2019L00396
	ed C88
	am F2020L00720; F2020L00946; F2021L00688; F2022L00600; F2022L01687; F2023L00770
Schedule 9A	
Schedule 9A	ad No 30, 2011
	am No 143, 2012; No 94, 2013; No 62, 2014; No 75, 2015; No 87, 2015; F2016L00109; F2016L00667; F2017L00552; F2017L00853; F2018L00311; F2018L00759; F2019L00396; F2020L00720
	ed C94
	am F2021L00688; F2022L00600; F2022L01300; F2023L00769; F2023L00770
Schedule 10	
Schedule 10 heading	rs. 1992 Nos. 332 and 370
	am. 1995 No. 208
	rs F2016L00109
Schedule 10	ad. 1992 No. 19
	am. 1992 No. 89; 1994 No. 150; 1995 No. 208
	rs. 1998 No. 227
	am No 62, 1999; No 29, 2000; No 78, 2004; No 26, 2010; No 102, 2011; F2016L00109; F2017L01561; F2020L00946
Schedule 11	ad. 1992 No. 89
	am. 1999 No. 324; 2002 No. 84
	rep. 2010 No. 26
Schedule 12	
Schedule 12	ad. 1992 No. 430
	am. 1995 No. 208; 2001 No. 159; 2003 No. 151; 2011 No. 102
	rs F2019L01660
Schedule 13	
Schedule 13	ad. 1995 No. 208
	am. 2001 No. 159; 2003 No. 151; 2011 No. 102
	rs F2019L01660
Schedule 14	
Schedule 14 heading	am. 1999 No. 62

Endnote 4—Amendment history

Provision affected	How affected
	rs. 2011 No. 102
Schedule 14	ad. 1997 No. 400
	rs. 1998 No. 227
	am F2018L00865
Schedule 15	ad. 2009 No. 228
	am F2016L00109
	rep F2018L00311
Schedule 16	
Schedule 16	ad No 30, 2011
	rs F2018L00865
	am F2019L01660