Therapeutic Goods Regulations 1990

Statutory Rules 1990 No. 394 as amended

made under the

Therapeutic Goods Act 1989

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Part 1 Preliminary

1 Name of Regulations [*see* Note 1]

 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.

***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.

***ASMI*** means Australian Self‑Medication Industry Incorporated (ABN 55 082 798 952).

***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.

***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 Medicines.

***CHCA*** means the Complementary Healthcare Council of Australia.

***Class 1 biological*** means a biological that is mentioned in Schedule 16 as a Class 1 biological.

*Note*At the time these Regulations commenced, there were no Class 1 biologicals.

***Class 2 biological*** means a biological that is:

 (a) both:

 (i) processed using only one or more of the actions of minimal manipulation; and

 (ii) for homologous use; or

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

***Class 3 biological*** means a biological that is:

 (a) processed:

 (i) using a method in addition to any of the actions of minimal manipulation; and

 (ii) in a way that does not change an inherent biochemical, physiological or immunological property; or

 (b) mentioned in Schedule 16 as a Class 3 biological.

***Class 4 biological*** means a biological that is:

 (a) processed:

 (i) using a method in addition to any of the actions of minimal manipulation; and

 (ii) in a way that changes an inherent biochemical, physiological or immunological property; or

 (b) mentioned in Schedule 16 as a Class 4 biological.

***Complaints Resolution Panel*** means the panel established under regulation 42R.

***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 an orphan drug designated under subregulation 16J (2).

***designated therapeutic goods*** means therapeutic goods other than:

 (a) therapeutic devices; and

 (b) goods included in Schedule 3 to the Poisons Standard that are not included in Appendix H of that standard; and

 (c) goods included in Schedule 4 or 8 to the Poisons Standard; and

 (d) biologicals.

***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.

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

***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*** means the repair, reconstruction, replacement, or supplementation of a recipient’s cells or tissues with a biological that performs the same basic function in the recipient as in the donor.

***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.

***minimal manipulation*** means a process involving any of the following actions:

 (a) centrifugation;

 (b) trimming, cutting or milling;

 (c) flushing or washing;

 (d) refrigeration;

 (e) freezing;

 (f) freeze drying (of structural tissues only);

 (g) the use of additives such as cryopreservatives, anticoagulants, antimicrobial agents;

 (h) irradiation for the purpose of bioburden reduction;

 (i) any other action that is similar to an action mentioned in paragraph (a), (b), (c), (d), (e), (f), (g) or (h).

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

***NFAA*** means the Nutritional Foods Association of Australia.

***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.

***official analyst*** means a person approved by the Secretary under regulation 25.

***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).

***orphan drug***has the meaning given by regulation 16H.

***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 Guidelines*** 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.

***rare disease*** means a disease, or condition, likely to affect not more than 2,000 individuals in Australia at any time.

***Required Advisory Statements for Medicine Labels*** means the document of that name published by the Therapeutic Goods Administration on 1 July 2004, as in force from time to time.

***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* definesStandards 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.

***the Act*** means the *Therapeutic Goods Act 1989*.

***Therapeutic Goods Advertising Code*** means the code made under section 42BAA 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.

***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);

 (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).

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).

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 recovery.

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 2 Advertisements for which approval is needed

5B Interpretation

 In this Division:

***applicant*** means an applicant for approval of an advertisement.

***approval holder***, in relation to an approved advertisement, means the person to whom notice of approval of the advertisement was given.

***withdraw***, in relation to an approved advertisement, includes withdrawal by any delegate under subregulation 5Q (2) or (3), whether or not that delegate gave the approval and, in the case of an approval given by the NFAA, includes a withdrawal by the CHCA.

5BA Means that are not *broadcast media*

 For the definition of ***broadcast media*** in section 42B of the Act, in relation to an advertisement to which this Division applies, each of the following means is declared to be an exempted means:

 (a) the Internet;

 (b) electronic mail;

 (c) narrowcast transmission, being a system the reception of which is limited:

 (i) by being targeted to special interest groups; or

 (ii) by being intended only for limited locations (for example, arenas or business premises); or

 (iii) by being provided during a limited period or to cover a special event; or

 (iv) because it provides programs of limited appeal; or

 (v) for any other reason;

 (d) short message service (SMS), being a system enabling the transmission of short text messages from a digital mobile telephone to another digital mobile telephone;

 (e) multimedia messaging service (MMS), being a system enabling the transmission of visual communication, voice communication or electronic mail from a digital mobile telephone to:

 (i) another digital mobile telephone; or

 (ii) an electronic mail address.

5C Application of Division

(1) This Division applies to advertisements for designated therapeutic goods published or inserted, or intended to be published or inserted, for valuable consideration, in specified media.

 (2) However, this Division does not apply to an advertisement that consists only of one or more of the following:

 (a) the brand name of the goods;

 (b) the price of the goods;

 (c) the type or style of the goods;

 (d) a photographic or other reproduction of the goods that does not contain any claim for therapeutic use in relation to the goods;

 (e) the locations or times at which the goods are offered for sale;

 (f) any other information reasonably necessary to identify the person offering the goods for sale.

5F Applications for approval of advertisements

 An application for approval of an advertisement must be:

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

 (b) signed by or on behalf of the applicant.

5G Approval of advertisements

 (1) If an application for approval of an advertisement is made and the prescribed fee is paid, the Secretary must approve the advertisement if the Secretary is satisfied that it:

 (a) complies with the Therapeutic Goods Advertising Code; and

 (b) does not contain a prohibited representation (whether in express terms or by necessary implication) about the goods; and

 (c) contains a required representation about the goods; and

 (d) does not contain an unacceptable presentation of the goods within the meaning of regulation 3A; and

 (e) does not contain a restricted representation about the goods the use of which has not been approved under section 42DF of the Act or permitted under subsection 42DK (1) of the Act.

 (3) Otherwise, the Secretary must refuse to approve the advertisement.

 (4) An approval may be subject to conditions imposed by the Secretary.

5H Notice of approval or refusal to approve an advertisement

(1) The Secretary must give written notice to the applicant of the approval of, or of the refusal to approve, an advertisement.

 (2) If written notice is not given to the applicant within 60 days after the day on which the application was made, or within such longer period as may be agreed in writing between the applicant and the Secretary, the Secretary is taken to have approved the advertisement at the end of the period.

 (3) If an approval is subject to conditions, the conditions must be set out in the notice.

 (4) A notice of refusal to approve an advertisement must:

 (a) give the Secretary’s reasons for the refusal; and

 (b) inform the applicant of the applicant’s right to have the Secretary’s decision reviewed by the Minister under regulation 5M.

5J Distinguishing numbers for approved advertisements

 (1)The Secretary must allocate a distinguishing number (the ***approval number***) to each approved advertisement.

 (2) The Secretary must inform the applicant of the approval number at the time of giving notice of the approval of the advertisement.

 (3) Unless the approval of the advertisement is withdrawn, an approval number expires at the end of 2 years from the date on which it is allocated.

5K Variation of conditions of approval

 (1) The Secretary, by written notice to an approval holder, may vary any condition of approval of an approved advertisement.

 (2) The notice must:

 (a) give the Secretary’s reasons for the variation; and

 (b) inform the approval holder of the approval holder’s right to have the Secretary’s decision reviewed by the Minister under regulation 5M.

5L Withdrawal of approval

(1)The Secretary, by written notice to an approval holder, may withdraw the approval of an approved advertisement if the Secretary is satisfied that:

 (a) information given by the applicant in the application was false or incorrect and the Secretary or the Minister relied on the information in deciding to approve the advertisement; or

 (b) a person has contravened section 42C of the Act in relation to the advertisement; or

 (c) there has been a breach of a condition of approval; or

 (d) because of a change to the facts or circumstances existing when the advertisement was approved, the advertisement no longer complies with the Therapeutic Goods Advertising Code; or

 (e) because of a change to the Therapeutic Goods Advertising Code, the advertisement no longer complies with the Code.

 (2) The Secretary, by written notice to an approval holder, may withdraw the approval of an approved advertisement on the recommendation of the Complaints Resolution Panel following a complaint to the Panel under subregulation 42ZCAB (1).

 (3) The notice under subregulation (1) or (2) must:

 (a) give the Secretary’s reasons for the decision; and

 (b) inform the approval holder of the approval holder’s right to have the Secretary’s decision reviewed by the Minister under regulation 5M.

5M Review by Minister of decisions of the Secretary

(1) An applicant or approval holder who is dissatisfied with a decision of the Secretary under regulation 5G, 5K or 5L may request the Minister, in writing, to review the decision.

 (2) The request must be made within 30 days after notice of the decision is given to the applicant or approval holder.

 (3) If an applicant requests a review of a decision of the Secretary under regulation 5G, the applicant must at the same time send a copy of the request to the Therapeutic Goods Advertising Code Council.

 (4) The Minister must reconsider the decision of the Secretary as soon as practicable after receiving a request, and may:

 (a) confirm the Secretary’s decision; or

 (b) revoke the Secretary’s decision and make a decision (including a decision to impose conditions) in substitution for the Secretary’s decision.

 (5) In making a decision under subregulation (4), the Minister must take into account any recommendation on the matter made by the Therapeutic Goods Advertising Code Council or the Complaints Resolution Panel, as the case requires.

 (6) Until a decision is made by the Minister, the making of a request does not affect the operation of the Secretary’s decision.

5N Notice of Minister’s decisions

 (1) The Minister must give written notice to the applicant or approval holder of the decision of the Minister under regulation 5M.

 (2) If, in making a decision on review of a decision by the Secretary under regulation 5G, the Minister does not accept a recommendation of the Therapeutic Goods Advertising Code Council, the Minister must notify the applicant of the fact.

 (3) If the Minister’s decision is to approve an advertisement subject to conditions, the conditions must be set out in the notice.

 (4) The notice must:

 (a) give the Minister’s reasons for the decision; and

 (b) inform the applicant or approval holder of the right of the applicant or approval holder to apply to the Administrative Appeals Tribunal under regulation 5P for a review of the Minister’s decision.

5P Review by Tribunal of decisions of the Minister

 An application may be made to the Administrative Appeals Tribunal for a review of a decision of the Minister under regulation 5M.

5Q Delegations

 (1) The Minister may delegate, in writing, a power or function of the Minister under regulation 5M or 5N to:

 (a) an officer of the Department; or

 (b) the National Manager, Therapeutic Goods Administration.

 (2) The Secretary may delegate, in writing, the Secretary’s power under regulation 5G to:

 (a) an officer of the Department; or

 (b) a medical practitioner registered in a State or internal Territory who is employed by the government of a State or Territory.

 (3) The Secretary may delegate to the CHCA the Secretary’s power under regulation 5G in relation to an advertisement about designated therapeutic goods that are complementary medicines if the advertisement is to be published or used in specified media of the kind mentioned in paragraph (a), (c) or (d) of the definition of ***specified media*** in section 42B of the Act.

 (4) The Secretary may delegate to the ASMI the Secretary’s power under regulation 5G in relation to:

 (a) an advertisement about designated therapeutic goods that are complementary medicines if the advertisement is to be broadcast in broadcast media; and

 (b) an advertisement about designated therapeutic goods that are not complementary medicines if the advertisement is to be published or broadcast in specified media.

 (5) The Secretary may delegate the Secretary’s power under regulation 5K or 5L in relation to a class of advertisements to a person if the Secretary has delegated to the person the Secretary’s power under regulation 5G for the same class of advertisements.

 (5A) The Secretary may delegate the Secretary’s power under subregulation 5L (2) to withdraw the approval of approved advertisements to the chairperson of the Complaints Resolution Panel.

 (6) A person exercising a power under a delegation under this regulation must comply with any conditions imposed or directions given by the Minister or Secretary, as the case requires.

Division 3 General provisions about advertising therapeutic goods

6 Restricted representations

 For subsection 42DD (1) of the Act, Part 2 of Appendix 6 to the Therapeutic Goods Advertising Code is prescribed.

6AA Prescribed committees

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

 (a) Advisory Committee on Non-prescription Medicines;

 (b) Advisory Committee on Complementary Medicines.

6A Approval of use of restricted representation — public interest criteria

 For paragraph 42DF (4) (c) of the Act, Part 2 of Appendix 6 to the Therapeutic Goods Advertising Code is prescribed.

6B Prohibited and required representations

 (1) For subsection 42DJ (1) of the Act, the following representations are prohibited representations:

 (a) the representations in column 2 of an item in Part 1 of Schedule 2 about therapeutic goods in column 3 of that item;

 (b) the representations in Part 1 of Appendix 6 to the Therapeutic Goods Advertising Code.

 (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 Exempt goods and exempt devices

 (1) For subparagraph 42DL (1) (h) (i) of the Act, the following exempt goods are prescribed:

 (a) goods that are exempt from the operation of Part 3‑2 of the Act under subregulation 12 (1A) or regulation 12A;

 (b) goods specified in item 1 of Schedule 5.

 (2) For subparagraph 42DL (1) (h) (i) of the Act, the following exempt devices are prescribed:

 (a) devices that are exempt from the operation of Division 3 of Part 4‑11 of the Act under subregulation 7.1 (2) or regulation 7.2 of the *Therapeutic Goods (Medical Devices) Regulations 2002*;

 (b) devices of a kind mentioned in item 1.1 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Division 4 Generic information about ingredients or components of therapeutic goods

8 Compliance with the Code

 For section 42DO of the Act, the principles stated in subsections 4 (1), (2), (3), (4), (5) and (6) of the Therapeutic Goods Advertising Code are specified.

8A Publication of generic information

 For paragraph 42DP (1) (b) of the Act, the principles contained in subsections 4 (1), (2), (3), (4), (5) and (6) of the Therapeutic Goods Advertising Code are specified.

Division 5 General

9 Orders about advertisements or generic information

 (1) On the recommendation of the Complaints Resolution Panel under subregulation 42ZCAI (3) in relation to an advertisement or generic information about therapeutic goods, the Secretary, by written notice, may order a person to do one or more of the following:

 (a) withdraw the advertisement or generic information;

 (b) publish a retraction;

 (c) publish a correction;

 (d) recover any advertisement or generic information that is still in circulation;

 (e) destroy the advertisement or generic information;

 (f) withdraw a particular claim or representation made by the advertisement or generic information, and not use that claim or representation in any other advertisement or generic information unless the person satisfies the Secretary that the use of the claim or representation would not result in a contravention of the Act, these Regulations or the Therapeutic Goods Advertising Code.

 (2) An order under subregulation (1) may be subject to conditions imposed by the Secretary.

 (3) The Secretary may delegate all or any of the Secretary’s powers under subregulation (1) to the chairperson of the Complaints Resolution Panel.

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 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 patient 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) are approved for registration on or after 4 July 1995;

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 patient 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; 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 patient 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) 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 registered goods; and

 (b) therapeutic goods, and classes of therapeutic goods, of a kind mentioned in Part 1 of Schedule 4 that are included in the Register are to be included in the part of the Register for listed goods.

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

 (1) If a person in relation to whom therapeutic goods are registered or listed dies, the legal personal representative 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 writing, of the death not later than 3 months after it occurred.

 (2) If a person in relation to whom therapeutic goods are registered or listed becomes bankrupt, the trustee in bankruptcy 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 writing, of the bankruptcy not later than 3 months after the person became bankrupt.

 (3) If a body corporate in relation to which therapeutic goods are registered or listed is being wound up, the liquidator 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, 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 the registration or listing of therapeutic goods;

then:

 (c) the person who acquires that business is taken to be the person in relation to whom the therapeutic goods are registered or listed; 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 the person in relation to whom the goods are to be registered or listed.

 (4A) If a person in relation to whom therapeutic goods are registered or listed:

 (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 person in the Register;

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 new name must be entered in the Register as the name of the person in relation to whom the therapeutic goods are registered or listed.

 (5) When a person notifies the Secretary of an event referred to in paragraph (1) (b), (2) (b), (3) (b) or (4) (d) or subregulation (4A), the person must send to the Secretary sufficient documentary evidence to establish the matter asserted in the notification.

 (6) If the Secretary is informed of the transfer of registration or listing of any therapeutic goods, or of the new name of a person and the circumstance giving rise to it, in accordance with this regulation, the Secretary must amend the Register accordingly.

 (7) If, at any time, the Secretary becomes aware that he or she has not been informed of the transfer of registration or listing in respect of any therapeutic goods, or of the new name of a person and the circumstance giving rise to it, in accordance with this regulation, the Secretary may cancel the registration or listing of those goods.

 (8) As soon as practicable after the Secretary has amended the Register in accordance with subregulation (6), the Secretary must give to the person in whose name the goods are registered or listed a certificate of registration or listing of the goods.

 (9) If the Secretary:

 (a) amends the Register in accordance with subregulation (6); or

 (b) cancels the registration or listing of goods under subregulation (7);

the person who has the certificate issued under subsection 25 (4) or 26 (4) of the Act or subregulation (8) must return it as soon as practicable to the Secretary.

Penalty:   5 penalty units.

 (10) An offence under subregulation (9) is an offence of strict liability.

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

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.

 (4) The Secretary must assign to grouped therapeutic goods that:

 (a) were in a gazetted therapeutic devices group or a gazetted therapeutic goods group when a registration or listing number was assigned, or last assigned, to the goods; and

 (b) are in a gazetted therapeutic devices group, or a gazetted therapeutic goods group, other than a group referred to in paragraph (a), 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

 (1) If a person in relation to whom a kind of medical device is included in the Register under Chapter 4 of the Act dies, the legal personal representative of the person:

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

 (b) must notify the Secretary, in writing, of the death within 3 months after it occurred.

 (2) If a person in relation to whom a kind of medical device is included in the Register under Chapter 4 of the Act becomes bankrupt, the trustee in bankruptcy 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 that Chapter; and

 (b) must notify the Secretary, in writing, of the bankruptcy within 3 months after the person became bankrupt.

 (3) If a body corporate in relation to which a kind of medical device is included in the Register under Chapter 4 of the Act is wound up, the liquidator 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 that Chapter; and

 (b) must notify the Secretary, in writing, of the winding up within 3 months after the body corporate is wound up.

 (4) If a person in relation to whom a kind of medical device is included in the Register under Chapter 4 of the Act:

 (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 entered in the Register;

the person must, within 3 months after the change of name or amalgamation:

 (c) notify the Secretary, in writing, of the new name of the person and the circumstance giving rise to it; and

 (d) return the certificate of the inclusion of the kind of device in the Register given under subsection 41FF (2) of the Act.

 (4A) If a person for whom a kind of medical device is included in the Register under Chapter 4 of the Act 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, the person to whom the business or interest is transferred or assigned:

 (a) is taken, to the extent of the business or interest transferred or assigned, to be the person for whom the medical device is included in the Register under Chapter 4 of the Act; and

 (b) must, within 3 months after the transfer or assignment, notify the Secretary in writing of the transfer or assignment.

 (5) If a person notifies the Secretary of an event under paragraph (1) (b), (2) (b), (3) (b) or (4A) (b), or a change of name under subregulation (4), the person must send to the Secretary sufficient documentary evidence to establish the matter asserted in the notification.

 (6) If, under subregulation (4), the Secretary is notified of a new name for a person in relation to whom a kind of medical device is included in the Register under Chapter 4 of the Act, the Secretary must:

 (a) enter the new name in the Register as the name of the person in relation to whom the kind of device is included in the Register under that Chapter; and

 (b) as soon as practicable after entering the new name, give to the person a new certificate of the inclusion of the kind of device in the Register under that Chapter.

 (7) If, at any time, the Secretary becomes aware that he or she has not been informed of a change in the name of a person in relation to whom a kind of medical device is included in the Register under Chapter 4 of the Act, the Secretary may cancel the entry in the Register in relation to the kind of device.

 (8) If, under this regulation, the Secretary:

 (a) changes the name of a person in relation to whom a medical device is included in the Register under Chapter 4 of the Act; or

 (b) cancels an entry in the Register in relation to a kind of medical device;

the Secretary must, as soon as practicable after changing the name or cancelling the entry:

 (c) notify the person in relation to whom the kind of device was included in the Register that the name has been changed or the entry in the Register has been cancelled; and

 (d) ask the person to return to the Secretary the certificate of the inclusion of the kind of device in the Register given under subsection 41FF (2) of the Act.

 (9) If a person in relation to whom a kind of device is included in the Register under Chapter 4 of the Act receives a notice under subregulation (8), the person must return to the Secretary, as soon as practicable after receiving the notice, the certificate of the inclusion of the kind of device in the Register under that Chapter that was given before the change of name or cancellation.

Penalty:   5 penalty units.

 (10) An offence against subregulation (9) is an offence of strict liability.

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

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

 (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.

 (2) If the person dies, that person’s legal personal representative:

 (a) is taken to be the person in relation to whom the biological is included in the Register under that Part; and

 (b) must notify the Secretary, in writing, of the death within 3 months after it occurred.

 (3) If the person becomes bankrupt, the trustee in bankruptcy of the estate of the person:

 (a) is taken to be the person in relation to whom the biological is included in the Register under that Part; and

 (b) must notify the Secretary, in writing, of the bankruptcy within 3 months after the person became bankrupt.

 (4) If the person is a body corporate that is being wound up, the liquidator of the body corporate:

 (a) is taken to be the person in relation to whom the biological is included in the Register under that Part; and

 (b) must notify the Secretary, in writing, of the winding up within 3 months after the body corporate is wound up.

 (5) 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:

 (a) notify the Secretary, in writing, of the new name of the person and the circumstance giving rise to it; and

 (b) return the certificate of the inclusion of the biological in the Register given under subsection 32DB (3) or 32DF (3) of the Act.

 (6) If the person transfers or assigns, in whole or in part, the business to which the biological relates or the person’s interest in the biological, the person to whom the business or interest is transferred or assigned:

 (a) is taken, to the extent of the business or interest transferred or assigned, 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 writing, of the transfer or assignment within 3 months after the transfer or assignment.

 (7) If a person notifies the Secretary of an event mentioned in paragraph (2) (b), (3) (b), (4) (b) or (6) (b), or a change of name under subregulation (5), the person must give the Secretary sufficient documentary evidence to establish the matter asserted in the notification.

 (8) If, under subregulation (5), the Secretary is notified of a new name for a person, the Secretary must:

 (a) enter the new name in the Register as the name of the person in relation to whom the biological is included in the Register under that Part; and

 (b) as soon as practicable after entering the new name, give to the person a new certificate of the inclusion of the biological in the Register under that Part.

 (9) If, at any time, the Secretary becomes aware that he or she has not been informed of a change in the name of a person in accordance with subregulation (5), the Secretary may cancel the entry in the Register in relation to the biological.

 (10) If, under this regulation, the Secretary changes the name of a person in relation to whom a biological is included in the Register under Part 3-2A of the Act or cancels an entry in the Register in relation to a biological, the Secretary must, as soon as practicable after changing the name or cancelling the entry:

 (a) notify the person that the name has been changed or the entry in the Register has been cancelled; and

 (b) ask the person to return to the Secretary the certificate of the inclusion of the biological in the Register given under subsection 32DB (3) or 32DF (3) of the Act.

 (11) If a person receives a notice under subregulation (10), the person must return to the Secretary, as soon as practicable after receiving the notice, the certificate of the inclusion of the biological in the Register under that Part that was given before the change of name or cancellation.

Penalty:   5 penalty units.

 (12) An offence against subregulation (11) is an offence of strict liability.

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

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 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;

 (v) the Required Advisory Statements for Medicine Labels;

 (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.

 (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.

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 the 9th Schedule to the Poisons Standard, as in force from time to time, 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 subsection 32CA (2) of the Act, all biologicals are exempt, subject to subregulation (2), from the operation of Division 4 of Part 3-2A of the Act.

 (2) The exemption of a medicine or biological is subject to 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) the medical practitioner by whom, or at whose direction, the medicine or biological is to be given to the person has signed a statement in relation to the person in the form approved by the Secretary for the purposes of this paragraph; 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.

 (3) A person who signs a statement referred to in subparagraph (2) (a) (iii) must send a copy of the statement to the Secretary within 4 weeks of signing it.

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 National Manager, Therapeutic Goods Administration, 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 Guidelines for Good Clinical Practice (the ***Practice Guidelines***), as in force from time to
time, published jointly by the International Conference
on Harmonisation on Technical Requirements for Registration of Pharmaceuticals for Human Use and the Committee for Medicinal Products; 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:

 (a) enter the 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 Guidelines;

 (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 special and experimental 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.

 (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.

 (4) For the purposes of subsection 19 (7) of the Act, the prescribed circumstances in which a therapeutic device, or a class of therapeutic devices, may be supplied in accordance with an authority under subsection 19 (5) of the Act are:

 (a) that, in each case, the medical practitioner authorised under subsection 19 (5) of the Act:

 (i) is a specialist engaged in clinical practice at a hospital; and

 (ii) is endorsed by the relevant ethics committee of the hospital; and

 (b) that the authority states the particular therapeutic intervention, or class of therapeutic intervention, for which the medical practitioner may supply the therapeutic device or class of therapeutic devices.

12C Exemptions for special and experimental uses — 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.

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:

 (a) in the case of a therapeutic device included in the part of the Register for registered goods — by writing the number so that it is clearly visible to the user:

 (i) on the label on the device; or

 (ii) on the label on the outermost level of packaging in which the device is to be supplied to its user;

 and, where more than one device is packaged for supply together, on the label on the outermost surface of the outermost package; and

 (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) “AUST L” in the case of listed goods;

 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) or (ii), is to be set out, and in that case the number and letters are to be set out in accordance with the direction.

15A Conditions of registration and listing of medicines

 For paragraph 28 (5) (e) of the Act, a person in relation to whom a medicine is registered or listed must comply with the requirements, if any, set out in the document published by the Therapeutic Goods Administration titled *Australian Requirements and Recommendations for Pharmacovigilance Responsibilities of Sponsors of Medicines*, as in force from time to time.

16 Listing of Therapeutic Goods

 (1) For the purposes of paragraph 26 (1) (g) of the Act, the therapeutic devices specified in Schedule 6 are prescribed.

16AA Documents and other information that may be required (Act subs 31 (2))

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

 (a) the quality of the goods;

 (b) the efficacy of the goods for the purposes for which the goods are to be used.

16AB Specified periods

 For paragraphs 32DQ (1) (c) and (2) (c) of the Act, 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 biological 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 biological or another person — within 30 days after the person first becomes aware of the event or occurrence.

Part 3A Applications for evaluation

Division 1 Goods mentioned in Part 1 of Schedule 10

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.

16B Notification of acceptance or rejection of application

 (1) If the Secretary receives an application:

 (a) under section 23 of the Act that requires an evaluation to which regulation 16C applies; or

 (b) to which regulation 16D applies;

he or she must send a notification in writing to the applicant that states whether the application has been accepted or rejected.

 (2) A notification must be sent:

 (a) if the application to which it relates is one that satisfies the conditions stated in subregulation 16C (4) or 16D (4) — within 20 working days; or

 (b) in any other case — within 40 working days;

of the day of receipt of the application.

16C Periods within which certain evaluations must be made

 (1) Subject to paragraph (4) (d), this regulation applies to an evaluation of a medicine that is a product of a kind specified in Part 1 of Schedule 10 if the application in relation to the evaluation:

 (a) is received by the Secretary on or after 1 February 1992; and

 (b) requires an evaluation under section 25 of the Act; and

 (c) is not an application to which subregulation 16G applies.

 (2) A reference in this regulation to a period in relation to an evaluation to which this regulation applies is a reference to the period that commences on the day on which the Secretary sends a notification to the applicant under regulation 16B that indicates acceptance of the application in relation to the evaluation.

 (3) An evaluation to which this regulation applies must be completed within whichever of the following periods applies:

 (a) if the evaluation satisfies the conditions stated in subregulation (4) — 175 working days;

 (b) in any other case — 255 working days.

 (4) The conditions referred to in paragraph (3) (a) are:

 (a) that the evaluation relates to a medicine that, in each of 2 acceptable countries, has been approved for general marketing;

 (b) that the formulation, directions for use and indications of the medicine are identical to those evaluated and approved for marketing in those 2 countries; and

 (c) that the Secretary has, in relation to the evaluation, 2 evaluation reports on the medicine that satisfy the requirements of subregulation (5); and

 (d) that the application is received by the Secretary on or after 1 September 1992.

 (5) The requirements referred to in paragraph (4) (c) for the evaluation reports (in this subregulation called ***the relevant reports***) are:

 (a) that the relevant reports were made respectively by a competent regulatory authority in each of the 2 countries referred to in paragraph (4) (b); and

 (b) that neither of the relevant reports is, wholly or in part, based on:

 (i) the other relevant report; or

 (ii) any other evaluation report that is a report on which the other relevant report was based; or

 (iii) any other evaluation report that is based on another report (being an evaluation report) if the other relevant report was based on that other report or any evaluation report that was based on that other report.

 (6) In this regulation:

***acceptable country*** means a country that the Minister has notified in the *Gazette* as an acceptable country for the purposes of this regulation.

***evaluation report*** does not include a report prepared by or on behalf of the applicant or sponsor and submitted to a regulatory authority in connection with an application for registration of, or variation of information in a register about, therapeutic goods.

***based on***, in relation to an evaluation report, includes compiled by reference to or in reliance on.

***relevant period***, in relation to an acceptable country, means the period stated in relation to the country in a notice under the definition of ***acceptable country***.

16D Periods within which certain applications must be decided

 (1) Subject to paragraph (4) (d), this regulation applies to an application (other than an application to which regulation 16F applies) concerning an evaluation of a medicine that is a product of a kind specified in Part 1 of Schedule 10 if the application:

 (a) is received by the Secretary on or after 1 February 1992; and

 (b) asks the Secretary under subsection 9D (3) of the Act to vary the entry of the medicine in the Register.

 (2) A reference in this regulation to a period, in relation to an evaluation of an application to which this regulation applies, is a reference to the period that commences on the day on which the Secretary sends a notification to the applicant under regulation 16B that indicates acceptance of the application.

 (3) An application to which this regulation applies must be decided, and notification given to the applicant, within whichever of the following periods applies:

 (a) if the application satisfies the conditions stated in subregulation (4) — 175 working days;

 (b) in any other case — 255 working days.

 (4) The conditions referred to in paragraph (3) (a) are:

 (a) that the application relates to a medicine that, in each of 2 acceptable countries, has been approved for general marketing;

 (b) that the formulation, directions for use and indications of the medicine are identical to those evaluated and approved for marketing in those 2 countries; and

 (c) that the Secretary has 2 evaluation reports on the medicine that satisfy the requirements of subregulation (5); and

 (d) that the application is received by the Secretary on or after 1 September 1992.

 (5) The requirements referred to in paragraph (4) (c) for the evaluation reports (in this subregulation called ***the relevant reports***) are:

 (a) that the relevant reports were made respectively by a competent regulatory authority in each of the 2 countries referred to in paragraph (4) (b); and

 (b) that neither of the relevant reports is, wholly or in part, based on:

 (i) the other relevant report; or

 (ii) any other evaluation report that is a report on which the other relevant report was based; or

 (iii) any other evaluation report that is based on another report (being an evaluation report) if the other relevant report was based on that other report or any evaluation report that was based on that other report.

 (6) The definitions in subregulation 16C (6) apply to this regulation.

16E Failure to decide an application within specified time

 The failure to decide, within the relevant time stated in paragraph 16D (3) (a) or (b), 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 under subsection 9D (3) of the Act — periods within which certain decisions must be made

 (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 Shorter evaluation period in certain cases

 (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 24 (1) 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

16GB Notification of acceptance or rejection of application

 (1) This regulation applies to an application:

 (a) under section 32DD of the Act that requires an evaluation to which regulation 16GC applies; and

 (b) to which regulation 16GD applies.

 (2) The Secretary must send a notification in writing to the applicant that states whether the application has been accepted or rejected.

 (3) A notification must be sent within 30 working days after the Secretary receives the application.

16GC Periods within which certain evaluations must be made

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

 (2) The evaluation must be completed within 255 working days after the Secretary sends a notification to the applicant under regulation 16GB that indicates acceptance of the application for the evaluation.

16GD Periods 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 asks 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) 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 regulation 16GB that indicates acceptance or rejection of the application.

16GE Failure to decide an application within specified time

 The failure to decide, within the time mentioned in subregulation 16GD (2), 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 32DD 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.

Part 3B Orphan drugs

16H Orphan drug

 (1) A medicine, vaccine or in vivo diagnostic agent is an ***orphan drug*** if it complies with this regulation.

 (2) It:

 (a) must be intended to treat, prevent or diagnose a rare disease; or

 (b) must not be commercially viable to supply to treat, prevent or diagnose another disease or condition.

 (3) It is not an orphan drug if any of the following persons or bodies has refused to approve it for use for the disease for a reason related to the medicine’s safety:

 (a) the Secretary;

 (b) the Food and Drug Administration of the United States of America;

 (c) the Medicines Control Agency of the United Kingdom;

 (d) the Bureau of Pharmaceutical Assessment of Canada;

 (e) the Medical Products Agency of Sweden;

 (f) the Medicines Evaluation Board of the Netherlands;

 (g) the European Agency for the Evaluation of Medicinal Products.

 (4) It is not an orphan drug if it has been registered for use for the disease or condition before 1 January 1998.

 (5) However, it may be registered before 1 January 1998 for another use or indication.

16I Application for orphan drug designation

 (1) The sponsor of an orphan drug may apply to the Secretary for the medicine to be designated as an orphan drug.

 (2) The application must be made using an application form approved by the Secretary.

 (3) The application must show why the medicine is an orphan drug.

 (4) For a vaccine or in vivo diagnostic agent, the application must also state that the vaccine or agent will be administered in Australia to not more than 2,000 people in each year after it is registered for use for the disease or condition.

*Note*   There is no fee for making the application: see subregulation 45 (12).

16J Orphan drug designation

(1) The Secretary must consider the application.

 (2) The Secretary must designate the medicine, in writing, as an orphan drug if the Secretary is satisfied that the statements made in the application are correct.

 (3) The Secretary must refuse to designate the medicine as an orphan drug if the Secretary is not satisfied that all of the statements made in the application are correct.

 (4) The Secretary must tell the applicant in writing, as soon as practicable after making the decision, whether the medicine has been designated.

*Note*   There is no fee for making the Secretary’s decision: see subregulation 45 (12).

 (5) If the Secretary designates the medicine, the Secretary must publish a notice in the *Gazette*, as soon as practicable after making the decision, giving the following information:

 (a) the sponsor’s name;

 (b) the medicine’s dose form and indication;

 (c) a statement that the medicine is a designated orphan drug.

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:

***relevant test***:

 (a) in relation to the analysis of therapeutic goods (other than medical devices), means a test that, under subregulation 28 (1), is a relevant test for the purpose of determining whether goods of a class in which the first‑mentioned goods are included are goods that conform with a standard applicable to the goods; and

 (b) in relation to the analysis of a medical device, means a test that, under subregulation 28 (2), is a relevant test for the purpose of determining whether a medical device of that kind complies with the applicable provisions of the essential principles.

***responsible analyst***, in relation to the analysis of a sample of therapeutic goods, means an 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 this Part, a sample of therapeutic goods is appropriately fastened and sealed if the sample is fastened and sealed:

 (a) in a vessel or package that is marked with the name and address of:

 (i) the person from whom the sample was taken; or

 (ii) for a sample delivered under subsection 28 (5A) or 41FN (2) of the Act — the sponsor of the goods; and

 (b) so as to prevent the opening of the vessel or package, and the removal of 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 Official analysts

 (1) The Secretary may, in writing, appoint a person who has appropriate qualifications and experience to be an official analyst for the purposes of these Regulations.

 (2) The Secretary is to maintain a register of the names of official analysts and is to cause those names to be published in the *Gazette* from time to time.

 (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 subsection 28 (5A) or 41FN (2) of the Act; and

 (c) nominate an official analyst to be the responsible analyst for a sample taken under paragraph (a) or delivered under subsection 28 (5A) or 41FN (2) of the Act.

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 packaged, 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 subsection 28 (5A) or 41FN (2) of the Act, the Secretary must as soon as practicable:

 (a) determine whether the sample is appropriately packaged, fastened and sealed; and

 (b) do either of the following:

 (i) if the sample is appropriately packaged, 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 packaged, fastened and sealed — return the sample to the sponsor of the goods, with a statement explaining in what way the sample is not appropriately packaged, 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 packaged, fastened and sealed; and

 (b) if the sample is appropriately packaged, 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 relevant tests to the extent the analyst considers necessary 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

 (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 Relevant tests

 (1) Each of the following is a relevant 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 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

 (c) a test specified in a monograph in the British Pharmacopoeia (Veterinary) in relation to that standard if:

 (i) those goods are for veterinary use; 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 relevant 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 official analyst

 (1) The responsible analyst must send to the sponsor of the goods a certificate signed by the analyst setting out the results of the examination and analysis.

 (2) The responsible analyst must send a copy of the certificate, signed by the analyst, to:

 (a) the Secretary; and

 (b) if the sample was taken under subregulation 25 (3) — the person from whom the sample was taken, if that person is not the sponsor of the goods.

 (3) The certificate and copies of the certificate of the official analyst must be sent to the persons referred to in subregulations (1) and (2) within a reasonable time of the completion of the analysis.

 (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;

the certificate, and the copy of it referred to in 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 certificate or copy is sent may ask for the results of the analysis referred to in the certificate 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 of an official analyst 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 of an official analyst issued under subregulation (1); or

 (b) a copy of that certificate;

and purporting to be signed by an official analyst is, in the absence of evidence to the contrary, to be taken to be the certificate or a copy of the certificate and to have been issued under subregulation (1) or (2), as the case requires.

30 Review of findings of official analyst

 (1) A person:

 (a) to whom a certificate, setting out the results of an examination and analysis of goods, is issued under subregulation 29 (1); 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 certificate, or the copy of the certificate, as the case may be.

 (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 an analyst who has appropriate qualifications and experience setting out:

 (a) a statement that the analyst 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 relevant tests in relation to the goods, 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, at the request of the sponsor of the goods, must direct:

 (a) if part of the sample remains unimpaired — the 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 an analyst agreed upon by the person who requested the review and the official analyst, or, in the absence of agreement, to an analyst nominated by the Secretary.

 (7) If a sample is forwarded to an analyst referred to in subregulation (6), the analyst is to:

 (a) analyse the sample of the goods in accordance with any relevant tests;

 (b) send to the Secretary a certificate, signed by the analyst, setting out the results of the analysis; and

 (c) send a copy of that certificate, signed by the analyst to the sponsor of the goods.

 (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 official analyst are upheld, the sponsor must pay any charges payable to the analyst referred to in subregulation (6) in respect of the analysis of the sample.

 (10) In proceedings under the Act or these Regulations, a certificate of an analyst 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 an analyst issued under subregulation (7); or

 (b) a copy of that certificate, and purporting to be signed by the analyst;

is, in the absence of evidence to the contrary, to be regarded as the certificate, or a copy of the certificate, and to have been issued under that subregulation.

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 subsection 28 (5A) or 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 subsection 28 (5A) or 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 1 Therapeutic Goods Committee

34 Establishment

 The Therapeutic Goods Committee is established.

34A Functions

 (1) The committee’s functions are as follows:

 (a) to advise and make recommendations to the Minister about the following:

 (i) the adoption of standards for therapeutic goods;

 (ii) matters relating to standards for therapeutic goods;

 (iii) requirements for labelling and packaging of therapeutic goods;

 (iv) standards for manufacture of therapeutic goods;

 (v) matters relating to medical device standards;

 (vi) matters relating to conformity assessment standards;

 (vii) matters relating to standards for biologicals;

 (b) to advise and make recommendations to the Minister or Secretary on matters referred to the committee by the Minister or Secretary.

 (2) The committee must:

 (a) give to the Minister and Secretary the reasons for any advice of the committee; and

 (b) for a matter mentioned in paragraph (1) (a) — consider:

 (i) the desirability of adopting any default standards or other recognised international standards for therapeutic goods in the interests of international harmonisation of therapeutic goods standards; and

 (ii) whether the application of those standards to Australian conditions is appropriate.

 (3) The Minister or Secretary may require the committee to give its advice to other persons or bodies.

34B Membership

 (1) The Minister may appoint, in writing, up to 12 persons to the committee in accordance with subregulation (2).

 (2) Each member of the committee must be a person who:

 (a) is nominated to the Minister in writing by a body that represents, or a combination of bodies that together represent, the interests of 1 of the following:

 (i) Australian manufacturers of prescription medicine products;

 (ii) Australian manufacturers of non-prescription medicine products;

 (iii) Australian manufacturers of complementary medicines;

 (iv) Australian manufacturers of medical devices and other therapeutic goods;

 (v) consumers of health services; or

 (b) has expertise in at least 1 of the following fields:

 (i) microbiology and virology;

 (ii) biomedical engineering;

 (iii) biological safety of biomaterials;

 (iv) biotechnology;

 (v) pharmaceutical science;

 (vi) community or hospital pharmacy practice.

Division 1A Advisory Committee on Prescription Medicines

35 Establishment

 The Advisory Committee on Prescription Medicines is established.

35A Functions

 (1) The committee’s functions are to advise and make recommendations to the Minister or Secretary about the following matters:

 (a) inclusion of a prescription medicine in the Australian Register of Therapeutic Goods (the ***Register***);

 (b) variation of an entry for a prescription medicine included in the Register;

 (c) removal or continued retention of a prescription medicine in the Register;

 (d) any other matter concerning a prescription medicine;

 (e) any other matter referred to the committee by the Minister or Secretary (whether or not related to prescription medicines).

 (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 32 persons to the committee in accordance with subregulations (2) and (3).

 (2) Each member of the committee must have expertise in at least 1 of the following fields:

 (a) general medical practice in Australia;

 (b) consumer issues;

 (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.

 (3) Membership of the committee must, to the extent reasonably practicable, represent the widest possible range of the fields mentioned in subregulation (2).

Division 1B Advisory Committee on Non‑prescription Medicines

36 Establishment

 The Advisory Committee on Non-prescription Medicines is established.

36A Functions

 (1) The committee’s functions are to advise and make recommendations to the Minister or Secretary about the following matters:

 (a) inclusion of a non-prescription medicine in the Australian Register of Therapeutic Goods (the ***Register***);

 (b) variation of an entry for a non-prescription medicine included in the Register;

 (c) removal or continued retention of a non-prescription medicine in the Register;

 (d) any other matter concerning a non-prescription medicine;

 (e) any other matters referred to the committee by the Minister or Secretary (whether or not related to non-prescription medicines).

 (2) The Minister or Secretary may require the committee to give its advice to other persons or bodies.

36B Membership

 (1) The Minister may appoint, in writing, up to 12 persons to the committee in accordance with subregulations (2) and (3).

 (2) Each member of the committee must have expertise in at least 1 of the following fields:

 (a) general medical practice in Australia;

 (b) specialist medical practice of a kind relevant to the committee’s functions;

 (c) pharmaceutical chemistry;

 (d) pharmacology;

 (e) toxicology;

 (f) microbiology;

 (g) community pharmacy;

 (h) manufacture of medicines;

 (i) consumer issues.

 (3) Membership of the committee must, to the extent reasonably practicable, represent the widest possible range of the fields mentioned in subregulation (2).

Division 1C Advisory Committee on the Safety of Medicines

37 Establishment

 The Advisory Committee on the Safety of Medicines is established.

37A Functions

 (1) The committee’s functions are to advise and make recommendations to the Minister or Secretary about the following matters:

 (a) safety of medicines;

 (b) risk assessment and risk management of medicines;

 (c) other matters related to pharmacovigilance;

 (d) any other matters referred to the committee by the Minister or Secretary (whether or not related to medicines safety).

 (2) The Minister or Secretary may require the committee to give its advice to other persons or bodies.

37B Membership

 (1) The Minister may, in writing, appoint up to 15 persons to the committee in accordance with subregulations (2) and (3).

 (2) Each member of the committee must have expertise in at least 1 of the following fields:

 (a) pharmacoepidemiology;

 (b) clinical pharmacology;

 (c) clinical pharmacy;

 (d) general medical practice in Australia;

 (e) general medicine;

 (f) complementary medicine;

 (g) paediatrics;

 (h) clinical immunology;

 (i) hepatology;

 (j) consumer issues.

 (3) Membership of the committee must, to the extent reasonably practicable, represent the widest possible range of the fields mentioned in subregulation (2).

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 to advise and make recommendations to the Minister or Secretary about the following matters:

 (a) inclusion of a medical device or other therapeutic goods in the Australian Register of Therapeutic Goods (the ***Register***);

 (b) variation of an entry for a medical device or other therapeutic goods in the Register;

 (c) removal or continued retention of a medical device or other therapeutic goods in the Register;

 (d) any matter concerning a medical device or other therapeutic goods;

 (e) any other matter referred to the committee by the Minister or Secretary (whether or not related to medical devices 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 32 persons to the committee in accordance with subregulations (2) and (3).

 (2) Each member of the committee must have expertise in at least 1 of the following fields:

 (a) medical or surgical expertise in 1 of the following fields:

 (i) gastroenterology;

 (ii) vascular;

 (iii) orthopaedics;

 (iv) neurology;

 (v) cardiology;

 (vi) plastic and reconstructive surgery;

 (vii) respiratory medicine;

 (viii) obstetrics or gynaecology;

 (ix) pathology;

 (x) anaesthetics;

 (xi) ophthalmology;

 (xii) dentistry;

 (xiii) ear nose and throat;

 (xiv) renal;

 (b) manufacture of medical devices;

 (c) consumer issues;

 (d) biomedical engineering;

 (e) biomaterials;

 (f) clinical medicine.

 (3) Membership of the committee must, to the extent reasonably practicable, represent the widest possible range of the fields mentioned in subregulation (2).

Division 1DA Advisory Committee on the Safety of Medical Devices

38C Establishment

 The Advisory Committee on the Safety of Medical Devices is established.

38D Functions

 (1) The committee’s functions are to advise and make recommendations to the Minister or Secretary about the following matters:

 (a) safety of medical devices;

 (b) risk assessment and risk management of medical devices;

 (c) other matters related to performance of medical devices;

 (d) any other matters referred to the committee by the Minister or Secretary (whether or not related to medical device safety).

 (2) The Minister or Secretary may require the committee to give its advice to other persons or bodies.

38E Membership

 (1) The Minister may appoint, in writing, up to 15 persons to the committee in accordance with subregulations (2) and (3).

 (2) Each member of the committee must have expertise in at least one of the following fields:

 (a) gastrointestinal surgery;

 (b) anaesthetics;

 (c) biomaterial science;

 (d) nursing;

 (e) cardiology;

 (f) cardio-thoracic surgery;

 (g) orthopaedic surgery;

 (h) epidemiology;

 (i) biomedical engineering;

 (j) neurosurgery;

 (k) human factors analysis;

 (l) oro-maxillofacial surgery;

 (m) consumer issues.

 (3) Membership of the committee must, to the extent reasonably practicable, represent the widest possible range of the fields mentioned in subregulation (2).

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 to advise and make recommendations to the Minister or Secretary about the following matters:

 (a) inclusion of a complementary medicine in the Australian Register of Therapeutic Goods (the ***Register***);

 (b) variation of an entry for a complementary medicine in the Register;

 (c) removal or continued retention of a complementary medicine in the Register;

 (d) any other matter concerning a complementary medicine;

 (e) any other matters referred to the committee by the Minister or Secretary (whether or not related to a complementary medicine).

 (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 12 persons to the committee in accordance with subregulations (2), (3) and (4).

 (2) Each member of the committee must have expertise in at least 1 of the following fields:

 (a) complementary medical practice;

 (b) manufacture of medicines;

 (c) consumer issues;

 (d) general medical practice in Australia;

 (e) herbal medicine;

 (f) naturopathy;

 (g) nutrition and nutritional medicine;

 (h) pharmacology;

 (i) pharmacognosy;

 (j) toxicology;

 (k) epidemiology.

 (3) At least 4 of the members of the committee must have clinical experience in at least 1 of the fields mentioned in subregulation (2).

 (4) Membership of the committee must, to the extent reasonably practicable, represent the widest possible range of the fields mentioned in subregulation (2).

Division 1EA Advisory Committee on Biologicals

39C Establishment

 The Advisory Committee on Biologicals is established.

39D Functions

 (1) The committee’s functions are to advise and make recommendations to the Minister or Secretary about the following matters:

 (a) inclusion of a biological in the Register under Part 3-2A of the Act;

 (b) variation of an entry for a biological included in the Register under Part 3-2A of the Act;

 (c) removal or continued inclusion of a biological in the Register under Part 3-2A of the Act;

 (d) any other matter concerning a biological;

 (e) any other matter referred to the committee by the Minister or Secretary (whether or not related to biologicals).

 (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 (2) and (3).

 (2) Each member of the committee must have expertise in at least one of the following fields:

 (a) infectious diseases;

 (b) tissue products;

 (c) blood products;

 (d) cellular therapies, including tissue engineering;

 (e) stem cell transplantation;

 (f) organ and tissue transplantation;

 (g) clinical expertise;

 (h) epidemiology or biostatistics;

 (i) toxicology;

 (j) consumer issues.

 (3) Membership of the committee must, to the extent reasonably practicable, represent the widest possible range of the fields mentioned in subregulation (2).

Division 1EB Advisory Committee on Safety of Vaccines

39F Establishment

 The Advisory Committee on the Safety of Vaccines is established.

39G Functions

 (1) The committee’s functions are to advise and make recommendations to the Minister or Secretary about the following matters:

 (a) safety of vaccines;

 (b) risk assessment and risk management of vaccines;

 (c) any other matters referred to the committee by the Minister or Secretary (whether or not they relate to vaccine safety).

 (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 (2), (3) and (4).

 (2) The Minister must appoint one member from each of the following:

 (a) the Australian Technical Advisory Group on Immunisation;

 (b) the National Immunisation Committee;

 (c) the Advisory Committee on the Safety of Medicines;

 (d) the National Centre for Immunisation Research and Surveillance.

 (3) The Minister may appoint up to 6 additional members, each with expertise in at least one of the following fields:

 (a) immunology;

 (b) virology;

 (c) bacteriology;

 (d) infectious diseases in adults;

 (e) infectious diseases in children;

 (f) public health;

 (g) epidemiology;

 (h) vaccine program implementation;

 (i) biostatistics;

 (j) consumer issues;

 (k) the provision of immunisation treatment by a general medical practitioner;

 (l) the provision of immunisation treatment by a nurse practitioner.

 (4) Membership of the committee must, to the extent reasonably practicable, represent the widest possible range of the fields mentioned in subregulation (3).

Division 1F General

40 Application of this Division

 This Division applies to committees mentioned in Divisions 1, 1A, 1B, 1C, 1D, 1DA, 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 National Manager of the Therapeutic Goods Administration, 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 2 Therapeutic Goods Advertising Code Council

42A Therapeutic Goods Advertising Code Council

 A committee, to be known as the Therapeutic Goods Advertising Code Council, is established.

42B Functions of the Council

 (1) The Council’s functions are:

 (a) to consider requirements for the advertising of therapeutic goods and changes to the Therapeutic Goods Advertising Code, to accept submissions for this purpose and to advise the Minister accordingly; and

 (b) to make recommendations to the Minister for achieving greater uniformity in approval processes and standards for advertising therapeutic goods in specified media and broadcast media; and

 (c) to make recommendations to the Minister about requests for review of a decision of the Secretary under regulation 5G; and

 (d) to consider matters raised at Council meetings by Council members or observers to the Council and advise the Minister accordingly; and

 (e) to advise the Minister on any matter referred to the Council by the Minister or Secretary; and

 (f) any other function conferred on the Council by these Regulations.

 (2) The Council may, with the approval of the Minister, appoint sub‑committees of its members to inquire into, and report on, any matter that is within the functions of the Council.

42C Membership of the Council

 (1) The Council is to have 15 members as follows:

 (a) 5 manufacturer/supplier members, comprising 1 person nominated by each of the following bodies:

 (i) the CHCA;

 (ii) the ASMI;

 (iii) the Australian Direct Marketing Association;

 (iv) the Direct Selling Association of Australia Inc;

 (v) the Medical Technology Association of Australia;

 (b) 2 advertising industry members, comprising 1 person nominated by each of the following bodies:

 (i) the Australian Association of National Advertisers;

 (ii) the Communications Council;

 (c) 2 consumer members, comprising 1 person nominated by each of the following bodies:

 (i) the Australian Consumers Association;

 (ii) the Consumers’ Health Forum;

 (d) 3 health care professional members comprising:

 (i) 1 person nominated by the Australian Traditional Medicines Society; and

 (ii) 1 person nominated jointly by the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia; and

 (iii) 1 person nominated by the Royal Australian College of General Practitioners;

 (e) 2 members nominated by the Therapeutic Goods Administration;

 (f) 1 member jointly nominated by the Publishers’ Advertising Advisory Bureau and the Outdoor Advertising Association of Australia.

 (2) A member of the Council who, before 1 January 1999, was nominated under paragraph (1) (a) by the NFAA is taken to have been nominated by the CHCA.

42D Term of office of Council members

(1) A member of the Council holds office for a term of 2 years from the date of the member’s nomination.

 (2) A person cannot hold office for more than 4 consecutive terms.

 (3) This regulation applies subject to:

 (a) regulation 42F (Resignation); and

 (b) regulation 42G (Cessation of membership).

42E Chairperson of the Council

(1) At the first meeting of the Council, and afterwards as the occasion arises, the Council must appoint a member of the Council to be the chairperson of the Council.

 (2) The chairperson must be a member nominated by the Therapeutic Goods Administration.

 (3) Unless the chairperson earlier resigns the office, or ceases to be a member of the Council, the chairperson holds office for 1 year from the date of his or her appointment.

42F Resignation

 (1) A member of the Council nominated by a body may resign as a member by notice in writing to the Council.

 (2) The chairperson of the Council may resign the office of chairperson by notice in writing to the Council.

42G Cessation of membership

 A person ceases to be a member of the Council if:

 (a) the person resigns as a member; or

 (b) the body who nominated the member nominates another person to be a member in place of the person first mentioned; or

 (c) the member is absent for 2 consecutive meetings of the Council without leave of the chairperson; or

 (d) the Council resolves to remove the member.

42H Alternate members

 (1) A body mentioned in regulation 42C may appoint up to 2 persons who are not members of the Council to each be available to be the alternate of a member nominated to the Council by that body.

 (2) If a member is absent from a meeting of the Council, the member’s alternate (if any) is entitled to attend the meeting and, when so attending, is taken to be a member of the Council.

 (3) If a person appointed by a body mentioned in regulation 42C ceases to hold office as a member:

 (a) the person who was the person’s alternate under subregulation (2) immediately before the person ceased to hold office; or

 (b) in the absence of an alternate under paragraph (a), a person who was, under subregulation (1), available to be the alternate of the person who ceased to hold office;

is entitled to attend meetings of the Council while the office is vacant and, when so attending, is taken to be a member of the Council.

 (3A) The person described in paragraph 3 (a) or (b) is taken to be the alternate of a person nominated to the vacant office until a new alternate is appointed.

 (4) A person appointed by a body as an alternate may resign the appointment by notice in writing to the body.

42J Observers to Council

(1) Each of the bodies mentioned in subregulation (2) may nominate a person to attend meetings of the Council as an observer.

 (2) For subregulation (1), the bodies are:

 (aa) the Australian Competition and Consumer Commission; and

 (b) ACCORD Australasia Ltd (ACN 117 659 168); and

 (ca) Medicines Australia; and

 (d) Medsafe, a regulatory agency within the New Zealand Ministry of Health.

 (2A) Free TV Australia and Commercial Radio Australia Limited may jointly nominate a person to attend meetings of the Council as an observer.

 (3) A person nominated as an observer is entitled, until the nomination is revoked:

 (a) to be given the agenda and minutes of Council meetings, as if the person were a member of the Council; and

 (b) by notice in writing to the chairperson suggest agenda items to be considered by the Council; and

 (c) if the person has given notice to the chairperson that the person intends to attend a meeting of the Council — to attend the meeting and vote on any question in accordance with regulation 42L.

 (4) The chairperson of the Complaints Resolution Panel may attend meetings of the Council as an observer having the same entitlements as an observer mentioned in subregulation (3).

42K Quorum

 At a meeting of the Council, a quorum consists of the chairperson and 5 other members of the Council including:

 (a) a member nominated by the CHCA or ASMI; and

 (b) an advertising industry member; and

 (c) a consumer member; and

 (d) a health care professional member; and

 (e) a member nominated by the Therapeutic Goods Administration.

42L Meetings

(1)Meetings of the Council are to be held at the times and places that the chairperson directs.

 (2) The chairperson is to preside at meetings of the Council at which he or she is present.

 (3) If the chairperson is absent from a meeting, a member nominated by the chairperson or, if no member is nominated, a member chosen by the members of the Council present at the meeting, is to preside.

 (4) A question (other than a question mentioned in subregulation (6)) arising at a meeting of the Council is to be decided by a majority of the votes of the members and observers present and voting, with the person presiding at the meeting having a casting vote.

 (5) An observer is entitled to vote at a meeting on any question affecting the interests of the body nominating the observer.

 (6) The chairperson is to decide whether a question affects the interests of the body nominating an observer.

42M Effect of vacancy

 The exercise of a power or the performance of a function of the Council is not affected by any vacancy in the membership of the Council.

42N Disclosure of interest

(1) A member of the Council (including a person taken to be a member under regulation 42H) who 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 Council must, as soon as possible after the relevant facts have come to the member’s knowledge, disclose the nature of the interest at a meeting of the Council.

 (2) The disclosure is to be recorded in the minutes of the meeting and the member must not, unless the Council otherwise determines:

 (a) be present during any deliberation of the Council with respect to the matter; or

 (b) take part in any decision of the Council with respect to that matter.

 (3) For the purpose of the making of a determination in relation to the member who has made the disclosure, any member who has a direct or indirect material personal interest (whether pecuniary or not) in the matter to which the disclosure relates must not:

 (a) be present during any deliberation of the Council for the purpose of making the determination; or

 (b) take part in the making of the determination by the Council.

 (4) Subregulations (1), (2) and (3) apply to an observer to the Council who is intending to take part in any decision of the Council on a matter as they apply to a member.

42P Procedure generally

 So far as these Regulations do not provide for the procedure of the Council, the Council may determine its own procedure.

42Q Annual report

 Within 3 months after the end of a financial year, the Council must give the Minister a written report on the operation of the Council for that financial year.

Division 3 Complaints Resolution Panel

Subdivision 1 General

42R Complaints Resolution Panel

 A committee, to be known as the Complaints Resolution Panel, is established.

42S Function of the Panel

 The function of the Panel is:

 (a) to receive and consider complaints about advertisements and generic information under Subdivision 2; and

 (b) to take action and to make recommendations to the Secretary on the complaints in accordance with that Subdivision.

42T Membership of the Panel

 (1) The panel is to have 9 members, as follows:

 (a) a chairperson nominated by the Therapeutic Goods Advertising Code Council;

 (b) 3 members, comprising 1 person nominated by each of the following bodies:

 (i) the CHCA;

 (ii) the ASMI;

 (iii) the Medical Technology Association of Australia;

 (c) 2 consumer members, comprising 1 person nominated by each of the following bodies:

 (i) the Australian Consumers Association;

 (ii) the Consumers’ Health Forum;

 (d) 3 health care professional members comprising:

 (i) 1 person nominated by the Australian Traditional Medicines Society; and

 (ii) 1 person nominated jointly by the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia; and

 (iii) 1 person nominated by the Royal Australian College of General Practitioners.

 (1A) However, the chairperson may nominate an additional member for a meeting of the Panel at which a complaint about a therapeutic device is to be considered.

 (1B) A person nominated under subregulation (1A) must:

 (a) have appropriate expertise and experience; and

 (b) be taken from a list of persons given to the chairperson by a body that represents, or a combination of bodies that together represent, the interests of Australian manufacturers, suppliers, exporters and importers of therapeutic devices.

 (2) A person cannot be nominated as a member of the Panel if the nomination would result in there being more than 5 members of the Panel who are members of the Therapeutic Goods Advertising Code Council.

 (3) A person cannot be nominated as a member of the Panel if the person is engaged in the process of approving advertisements for the CHCA or ASMI, under a delegation to the CHCA or ASMI under regulation 5Q.

 (4) A member of the Panel who, before 1 January 1999, was nominated under paragraph (1) (b) by the NFAA is taken to have been nominated by the CHCA.

42U Term of office of Panel members

 (1) A member of the Panel holds office for a term of 2 years from the date of the member’s nomination.

 (2) A person cannot hold office for more than 4 consecutive terms.

 (3) This regulation applies subject to regulation 42V (Cessation of office).

42V Cessation of office

 A person ceases to be a member of the Panel if:

 (a) the person resigns as a member by notice in writing to the Panel; or

 (b) the body who nominated the member nominates another person to be a member in place of the person first mentioned; or

 (c) the Panel resolves to remove the member.

42W Alternate members

 (1) The chairperson may appoint a person who is not a member of the panel to be the alternate chairperson of the Panel.

 (2) A body mentioned in paragraph 42T (1) (b), (c) or (d) may appoint up to 2 persons who are not members of the Panel to each be available to be the alternate of a member nominated to the Panel by that body.

 (3) If a member (including the chairperson) is absent from a meeting of the Panel, the member’s alternate (if any) is entitled to attend the meeting and, when so attending, is taken to be a member of the Panel.

 (3A) If a person appointed by a body mentioned in paragraph 42T (1) (b), (c) or (d) ceases to hold office as a member:

 (a) the person who was the person’s alternate under subregulation (3) immediately before the person ceased to hold office; or

 (b) in the absence of an alternate under paragraph (a), a person who was, under subregulation (2), available to be the alternate of the person who ceased to hold office;

is entitled to attend meetings of the Council while the office is vacant and, when so attending, is taken to be a member of the Council.

 (3B) The person described in paragraph 3A (a) or (b) is taken to be the alternate of a person nominated to the vacant office until a new alternate is appointed.

 (4) If the chairperson ceases to hold office:

 (a) the person who was the person’s alternate immediately before the person ceased to hold office is entitled to attend meetings of the Panel while the office is vacant and, when so attending, is taken to be a member of the Panel; and

 (b) the person is taken to be the alternate of a person nominated to the vacant office until a new alternate is appointed.

 (5) A person appointed by a body as an alternate may resign the appointment by notice in writing to the body.

42X Observers to Panel

 (1) The Therapeutic Goods Administration must nominate a person to attend meetings of the Panel as an observer.

 (2) Food Standards Australia New Zealand may nominate a person to attend meetings of the Panel as an observer.

 (3) A person nominated as an observer is entitled, until the nomination is revoked:

 (a) to be given the agenda and minutes of Panel meetings, as if the person were a member of the Panel; and

 (b) by notice in writing to the chairperson suggest agenda items to be considered by the Panel; and

 (c) to attend meetings of the Panel and vote on any question in accordance with regulation 42Z.

42Y Quorum

 (1) Subject to subregulation (3), at a meeting of the Panel, a quorum exists if the chairperson and 4 other persons, being members of the Panel or observers to the Panel, are present.

*Note*   See regulation 42T in relation to the nomination of members of the Panel and regulation 42X in relation to the nomination of observers to the Panel.

 (3) A quorum for a meeting convened to consider a complaint does not include a member of the Panel if the complaint was made by:

 (a) the member; or

 (b) the body that nominated the member.

42Z Meetings

 (1)Meetings of the Panel are to be held at the times and places that the chairperson directs.

 (2) The chairperson is to preside at meetings of the Panel at which he or she is present.

 (3) If the chairperson or chairperson’s alternate is absent from a meeting, a member nominated by the chairperson or, if no member is nominated, a member chosen by the members of the Panel present at the meeting, is to preside.

 (4) A question arising at a meeting of the Panel is to be decided by a majority of the votes of the members and observers present and voting, with the person presiding at the meeting having a casting vote.

 (5) An observer is entitled to vote at a meeting on any question affecting the interests of the body nominating the observer.

42ZA Effect of vacancy

 The exercise of a power or performance of a function of the Panel is not affected by any vacancy in the membership of the Panel.

42ZB Disclosure of interest

(1) A member of the Panel (including a person taken to be a member under regulation 42W) who 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 Panel must, as soon as possible after the relevant facts have come to the member’s knowledge, disclose the nature of the interest at a meeting of the Panel.

 (2) The disclosure is to be recorded in the minutes of the meeting and the member must not, unless the Panel otherwise determines:

 (a) be present during any deliberation of the Panel with respect to the matter; or

 (b) take part in any decision of the Panel with respect to that matter.

 (3) For the purpose of the making of a determination in relation to the member who has made the disclosure, any member who has a direct or indirect material personal interest (whether pecuniary or not) in the matter to which the disclosure relates must not:

 (a) be present during any deliberation of the Panel for the purpose of making the determination; or

 (b) take part in the making of the determination by the Panel.

 (4) Subregulations (1), (2) and (3) apply to an observer to the Panel who is intending to take part in any decision of the Panel on a matter as they apply to a member.

42ZC Reports to Council

 (1) The Panel must give to the Therapeutic Goods Advertising Code Council periodic written reports on the operation of the Panel during a reporting period.

 (2) Each reporting period must be for a consecutive period of not more than 12 months.

 (3) The Panel must consult with the Therapeutic Goods Advertising Code Council to determine the first reporting period.

 (4) A report must be given as soon as practicable after the end of the reporting period to which it relates.

Subdivision 2 Procedure — Complaints about advertisements and generic information

42ZCAA Definitions for Subdivision 2

 In this Subdivision:

***another authority*** includes the Therapeutic Goods Administration.

***complaint*** means a complaint about an advertisement or generic information made to the Complaints Resolution Panel in accordance with regulation 42ZCAB.

***person apparently responsible***, in relation to a complaint about an advertisement or generic information,means the person who, based on the complaint and the assessment of the Complaints Resolution Panel, appears to be responsible for requesting the publication or insertion of the advertisement or generic information in specified media.

42ZCAB Complaints about advertisements or generic information

 (1) A person may complain in writing to the Complaints Resolution Panel that:

 (a) an advertisement about designated therapeutic goods that is published or inserted in specified media or broadcast media contravenes:

 (i) subsection 22 (5) or section 42C, 42DL, 42DM or 42DP of the Act; or

 (ii) these Regulations; or

 (iii) the Therapeutic Goods Advertising Code; or

 (b) an advertisement about medical devices or other therapeutic goods that is published or inserted in specified media or broadcast media contravenes:

 (i) subsection 22 (5) or 41FN (5) of the Act; or

 (ii) these Regulations; or

 (iii) the Therapeutic Goods Advertising Code.

 (2) A person may complain in writing to the Complaints Resolution Panel that generic information, to which Division 4 of Part 5‑1 of the Act applies, that is published or inserted in specified media or broadcast media contravenes that Division.

42ZCAC Procedure on receipt of a complaint

(1)If the Panel receives a complaint, the Panel:

 (a) must give, to the complainant (if known) and the person apparently responsible, written notice that the complaint has been received; and

 (b) may make initial inquiries so that the details and background of the complaint are available to the Panel when it considers the complaint

 (2) The notice must:

 (a) give details of the complaint; and

 (b) invite the complainant (if known) and the person apparently responsible to send written submissions to the Panel, together with any supporting documents.

42ZCAD Dealing with complaint

(1) The Panel must consider a complaint and decide whether the complaint is justified.

 (2) In considering the complaint, the Panel must have regard to:

 (a) any written submissions and documents given to the Panel; and

 (b) the results of its inquiries (if any); and

 (c) information obtained about the complaint.

 (3) A member of the Panel must not participate in the Panel’s consideration of a complaint if the complaint was made by:

 (a) the member; or

 (b) the body that nominated the member.

42ZCAE Powers of Panel

 (1) The Panel may inform itself on any matter, and consult such persons, as it thinks fit.

 (2) The Panel may require the person apparently responsibleor the sponsor to produce evidence in support of a claim made in an advertisement or in generic information that is the subject of a complaint.

42ZCAF Withdrawal of complaint

(1) The complainant may withdraw a complaint at any time.

 (2) The Panel may treat a complaint as withdrawn if, before dealing with the complaint under regulation 42ZCAD, the Panel is satisfied that:

 (a) the complaint is trivial, vexatious, misconceived or lacking in substance; or

 (b) the subject matter of the complaint has been dealt with by the Panel or by another authority; or

 (c) the subject matter of the complaint can more effectively or conveniently be dealt with by another authority; or

 (d) both:

 (i) the complainant does not intend to proceed with the complaint; and

 (ii) on the basis of the complaint, there does not appear to have been any contravention of the Act, these Regulations or the Therapeutic Goods Advertising Code.

 (3) If the complaint is withdrawn under subregulation (1), the Panel must inform the person apparently responsible of the fact.

 (4) If the Panel treats a complaint as withdrawn under subregulation (2), the Panel must give written notice to the complainant (if known) and the person apparently responsible of the Panel’s decision and the reasons for the decision.

42ZCAG Dealing with subject matter despite withdrawal of complaint

 (1) The Panel may deal with the subject matter of a complaint despite the withdrawal of the complaint if it appears to the Panel that there may have been a contravention of the Act, these Regulations or the Therapeutic Goods Advertising Code.

 (2) If the Panel decides to deal with the subject matter of a complaint under subregulation (1), the Panel must give written notice of its decision and the reasons for the decision to the person apparently responsible.

42ZCAGA Panel may refer complaint to another authority

 (1) If the Panel is satisfied that:

 (a) the subject matter of a complaint, or the advertisement or generic information to which a complaint relates, involves a matter that could more effectively or conveniently be dealt with by another authority; and

 (b) a complaint relating to the matter could have been made by the complainant to the authority;

the Panel may, in writing, refer the matter, and any material before the Panel relating to the matter, to the authority.

 (2) If the Panel refers a matter to another authority, the Panel must give written notice of its decision to the complainant (if known) and the person apparently responsible.

 (3) The referral of a matter under subregulation (1) does not prevent the Panel from dealing with other matters to which the complaint relates in accordance with this Subdivision.

 (4) This regulation applies despite the withdrawal of the complaint.

42ZCAH Dealing with matters not specified in complaint

 (1) The Panel may deal with a matter that is not mentioned in a complaint if it is satisfied that the advertisement or generic information to which the complaint relates may contravene the Act, these Regulations or the Therapeutic Goods Advertising Code in some other way

 (2) If the Panel decides to deal with a matter under subregulation (1), the Panel must give written notice of its decision to the person apparently responsible.

 (3) The notice must:

 (a) give details of the matter not mentioned in the complaint and the possible contravention of the Act, these Regulations or the Therapeutic Goods Advertising Code that are to be dealt with by the Panel; and

 (b) invite the person apparently responsible to send written submissions to the Panel, together with any supporting documents.

 (4) This regulation applies despite the withdrawal of the complaint.

42ZCAI Action that Panel may take

 (1) If, in relation to a complaint about an advertisement, the Panel is satisfied that there has been a contravention of the Act, these Regulations or the Therapeutic Goods Advertising Code, the Panel may request in writing the person apparently responsible to do one or more of the following:

 (a) withdraw the advertisement;

 (b) publish a retraction;

 (c) publish a correction;

 (d) withdraw a particular claim or representation made by the advertisement, and give the Panel a written undertaking not to use that claim or representation in any other advertisement unless the person apparently responsible satisfies the Panel that the use of the claim or representation would not result in a contravention of the Act, these Regulations or the Therapeutic Goods Advertising Code.

 (2) If, in relation to a complaint about generic information, the Panel is satisfied that there has been a contravention of the Act, these Regulations or the Therapeutic Goods Advertising Code, the Panel may request in writing the person apparently responsible to do one or more of the following:

 (a) withdraw the generic information;

 (b) publish a retraction;

 (c) publish a correction;

 (d) withdraw a particular claim or representation made by the generic information, and give the Panel a written undertaking not to use that claim or representation in any other generic information unless the person apparently responsible satisfies the Panel that the use of the claim or representation would not result in a contravention of the Act, these Regulations or the Therapeutic Goods Advertising Code.

 (3) If the person apparently responsible:

 (a) does not comply with a request under subregulation (1) or (2) within 14 days after the request is made; or

 (b) breaches an undertaking given under paragraph (1) (d) or (2) (d);

 the Panel may make a recommendation to the Secretary about the advertisement or generic information.

 (4) Without limiting subregulation (3), the Panel may recommend that the Secretary do one or more of the following:

 (a) if the advertisement is an approved advertisement — withdraw the approval of the advertisement;

 (ab) suspend the registration or listing of goods under subsection 29D (1) of the Act;

 (b) cancel the registration or listing of the goods under section 30 of the Act;

 (ba) order the withdrawal of the advertisement or generic information;

 (c) order the publication of a retraction;

 (d) order the publication of a correction;

 (e) order the recovery of any advertisement or generic information that is still in circulation;

 (f) order the destruction of the advertisement or generic information;

 (g) suspend a kind of medical device from the Register under Part 4‑6 of the Act;

 (h) cancel the entry of a kind of medical device from the Register under Part 4‑6 of the Act;

 (i) order that a particular claim or representation made by the advertisement or generic information be withdrawn, and not be used in any other advertisement or generic information unless the person apparently responsible satisfies the Panel that the use of the claim or representation would not result in a contravention of the Act, these Regulations or the Therapeutic Goods Advertising Code.

 (5) The Panel must give written notice of a decision under subregulation (1) or (2), or a recommendation under subregulation (3), to the complainant (if known) and the person apparently responsible, setting out its reasons.

42ZCAJ Dealing with complaint if court proceedings begun

 (1) The Panel must not deal with a complaint if a proceeding has begun in a court about the subject matter of the complaint and the proceeding has not been finally disposed of.

 (2) If, after a complaint has been made to the Panel, a proceeding begins in a court about the subject matter of the complaint, the Panel must not deal with the complaint until the proceeding is finally disposed of.

 (3) However, subregulations (1) and (2) do not apply if the panel decides to deal with a complaint after taking into account the following matters:

 (a) whether either of the following would be unreasonably disadvantaged if the Panel were to deal with the complaint before the proceeding had been finally disposed of:

 (i) the person making the complaint (if known to the Panel);

 (ii) the person apparently responsible;

 (b) whether the complaint could be referred to another authority under regulation 42ZCAGA;

 (c) the public interest;

 (d) any other matter the Panel thinks relevant.

 (4) If, after taking into account the matters mentioned in subregulation (3), the Panel decides to deal with a complaint, the Panel must give written notice of its decision to:

 (a) the person making the complaint (if known to the Panel); and

 (b) the person apparently responsible.

42ZCAK Procedure generally

 So far as these Regulations do not provide for the procedure of the Panel, the Panel may determine its own procedure.

42ZCAL Register of complaints

 (1) The Panel may publish, including on the Internet, a register of complaints and related information.

 (2) The register may include copies of, and information about, the following:

 (a) complaints received by the Panel;

 (b) decisions made by the Panel under regulation 42ZCAD in relation to complaints;

 (c) action taken by the Panel under regulation 42ZCAI in relation to complaints;

 (d) statements of reasons given for decisions or action mentioned in paragraph (b) or (c);

 (e) any other information that the Panel considers appropriate.

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 6 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 two‑thirds 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 6 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 two‑thirds 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 asubmission 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 (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

 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 persons who made a submission in response to the original invitation under paragraph 42ZCZK (1) (d) to make further submissions to the Secretary in relation to the interim decision within 10 business days after publication of the notice (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.

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 Charges for registration, listing and inclusion of medical devices and biologicals

43AAA Time for payment of charge

 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 must be paid by no later than the last day of the second month after the month when the goods were entered in the Register.

Subdivision 2 Low value turnover

43AAB Definitions

 In this Subdivision:

***approved person*** means a person who is a qualified accountant under section 88B of the *Corporations Act 2001*, but does not include:

 (a) a person who, under this Subdivision, is required to submit to the Secretary a statement signed by an approved person; or

 (b) an employee of that person.

***existing entry***, for a therapeutic good (other than a biological), means an entry for registration, listing or inclusion of the therapeutic good (other than a biological) in the Register that is not a new entry.

***low value turnover*** means a turnover of not more than 15 times the annual registration charge, the annual listing charge or the annual charge for inclusion in the Register (other than the annual charge for inclusion in the Register of a biological under Part 3-2A of the Act) payable for a financial year.

***new entry***,for a therapeutic good (other than a biological), means an entry for registration, listing or inclusion of the therapeutic good (other than a biological) in the Register that commenced in the financial year.

***turnover***, for a therapeutic good (other than a biological), means gross dollar receipts (excluding GST) from sales of the therapeutic good (other than a biological) in Australia for a financial year, including retail and wholesale sales.

43AAC Application requirements

 (1) For section 44A of the Act, the person liable to pay the annual registration charge, the annual listing charge or the annual charge for inclusion of a therapeutic good (other than a biological) in the Register may apply to the Secretary for an exemption from liability to pay the charge for the current financial year on the ground that the turnover of that good for the applicable financial year is a low value turnover.

 (2) The application must be:

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

 (b) accompanied by:

 (i) for an existing entry — a statement of the actual turnover of the therapeutic good for the previous financial year signed by an approved person; or

 (ii) for a new entry — a statement of the estimated turnover of the therapeutic good for the current financial year signed by the person liable to pay the charge; and

 (iii) subject to regulation 45A, the fee payable; and

 (c) received by the Secretary:

 (i) for an existing entry — before 2 September of the financial year; and

 (ii) for a new entry — at least 21 days before the date for payment mentioned in regulation 43AAA.

 (3) The statements mentioned in subparagraphs (2) (b) (i) and (ii) must be in a form approved by the Secretary.

43AAD Decision by the Secretary — exemption application

 (1) Within 21 days after receiving an application under subregulation 43AAC (1), the Secretary must:

 (a) decide whether to grant the exemption; and

 (b) give written notice to the person of the decision; and

 (c) if the decision is a refusal, the reasons for the decision.

 (2) If the Secretary refuses to grant the exemption, the applicant must pay the charge for which exemption was sought:

 (a) for an existing entry — within the later of:

 (i) 14 days after the notice is given under paragraph (1) (b); or

 (ii) the date mentioned in paragraph 44 (1) (b) of the Act; and

 (b) for a new entry — within the later of:

 (i) 14 days after the notice is given under paragraph (1) (b); or

 (ii) the date mentioned in regulation 43AAA.

43AAE Actual turnover — new entries in the Register

 (1) If an exemption has been granted under subregulation 43AAD (1)  for a new entry in the Register based on the estimated turnover of a therapeutic good (other than a biological) for a financial year (the ***current year***), the person must give to the Secretary by 1 September in the following financial year (the ***following year***):

 (a) details, in writing in a form approved by the Secretary, of the actual turnover of the therapeutic good (other than a biological) for the current year; and

 (b) a signed statement by an approved person, in a form approved by the Secretary, of the actual turnover of the therapeutic good (other than a biological) for the current year.

 (2) Before 1 September in the following year, the person may apply in writing for, and the Secretary may agree to, an extension of up to 28 days after the time mentioned in subregulation (1) for giving the information.

 (3) If the person does not give the information to the Secretary within the time mentioned in subregulation (1) or within the extended time agreed to by the Secretary under subregulation (2):

 (a) the exemption is taken to be cancelled on 30 September in the following year; and

 (b) the person must pay the charge for which the exemption was granted by 31 October in the following year.

Exemptions for financial years commencing 1 July 2009 and 1 July 2010

 (4) Subregulations (1), (2) and (3) are taken not to have applied to a person if:

 (a) an exemption was granted to the person under subregulation 43AAD (1) for a new entry in the Register based on the estimated turnover of a therapeutic good for either of the financial years commencing on 1 July 2009 or 1 July 2010; and

 (b) for either or both of the financial years mentioned in paragraph (a), the person did not give to the Secretary the information mentioned in paragraphs (1) (a) and (b) by the time mentioned in subregulation (1).

 (5) If subregulation (4) applies to a person, the Secretary may, by written notice given to the person, specify a date by which the person must provide the following information to the Secretary:

 (a) details, in a form approved by the Secretary, of the actual turnover of the therapeutic good, for the financial year or financial years for which the person was required to give the Secretary the information mentioned in paragraphs (1) (a) and (b);

 (b) a signed statement by an approved person, in a form approved by the Secretary, of the actual turnover of the therapeutic good for that financial year or those financial years.

 (6) A date specified in a notice mentioned in subregulation (5) must not be less than 2 months after the date of the notice.

 (7) If a person to whom subregulation (4) applies does not give the information mentioned in subregulation (5) to the Secretary by the date specified in the notice:

 (a) the exemption is taken to be cancelled on the day after the date specified in the notice; and

 (b) the person must pay the charge for which the exemption was granted within 2 months after the day specified in the notice.

43AAF Decision based on actual turnover

 (1) Within 21 days after receiving the information mentioned in subregulation 43AAE (1) or (5), the Secretary must:

 (a) decide whether the actual turnover of the therapeutic good was a low value turnover; and

 (b) give to the person written notice of:

 (i) the decision; and

 (ii) if the decision is that the actual turnover was not a low value turnover — the reasons for the decision.

 (2) If the Secretary decides that the turnover of the therapeutic good for the financial year was not a low value turnover and gives the person a notice under paragraph (1) (b), then:

 (a) the exemption is cancelled; and

 (b) the person who receives the notice mentioned in paragraph  (1) (b) must pay the charge for which the exemption has been granted:

 (i) if the exemption relates to a financial year other than the financial year commencing on 1 July 2009 or 1 July 2010—by 31 October of the following year; and

 (ii) if the exemption relates to the financial year commencing on 1 July 2009 or 1 July 2010—within 2 months after the day specified in the notice.

43AAG Requests by Secretary for additional information

 (1) This regulation applies to a person who has been granted an exemption under regulation 43AAD.

 (2) Within 2 years after the end of the financial year to which the charge for which the exemption was granted relates, the Secretary may, by notice in writing, ask the person for additional information or documents in relation to the granting of the exemption.

(3) The person must give the information or documents within 28 days after the notice is given under subregulation (2).

 (4) The person may apply in writing for, and the Secretary may agree to, an extension of up to 28 days after the time mentioned in subregulation (3) for giving the information or documents.

 (5) If the person does not give the information or documents within the time mentioned in subregulation (3) or within the extended time agreed to by the Secretary under subregulation (4), the exemption is taken to be cancelled.

 (6) If an exemption is cancelled under subregulation (5), the person must within 14 days after the day of cancellation, pay the charge for which the exemption was granted.

43AAH Decision by the Secretary — new information

 (1) The Secretary must within 21 days after receiving the information or documents mentioned in subregulation 43AAG (2):

 (a) decide whether the turnover of the therapeutic good for the applicable financial year was a low value turnover; and

 (b) give to the person written notice of:

 (i) the decision; and

 (ii) if the decision is that the turnover was not a low value turnover — reasons for the decision.

 (2) If the Secretary decides that the turnover of the therapeutic good for the applicable year was not a low value turnover and gives the person a notice under paragraph (1) (b), then:

 (a) the exemption is cancelled; and

 (b) within 14 days after the date of the notice mentioned in paragraph (1) (b), the person must pay the charge for which the exemption had been granted.

43AAI Appeal to AAT

 The person may appeal to the Administrative Appeals Tribunal for review of a decision made under the following provisions:

 (a) paragraph 43AAD (1) (a);

 (b) paragraph 43AAF (1) (a);

 (c) paragraph 43AAH (1) (a).

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 $85 900 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 subregulation 3 (2) of the *Therapeutic Goods (Charges) Regulations 1990* 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 of Schedule 9 is prescribed for the matter that, for that fee, is mentioned in column 2 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 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?

 (1) A fee is not payable in accordance with item 2 or 3 of Schedule 9 for an application for the registration or listing of a therapeutic device if:

 (a) the device was included in the Register under regulation 10B immediately before the application is made; and

 (b) the application is made because the effect of an amendment of these Regulations is that:

 (i) the device ceases to be required to be listed and becomes required to be registered; or

 (ii) the device ceases to be required to be registered and becomes required to be listed.

 (2) The applicable fee under item 2 or 3 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.

 (3) An application fee is taken not to have been payable for an application for the registration of a therapeutic good made in accordance with section 23 of the Act if:

 (a) the application was made during the period:

 (i) beginning on 1 August 1998 and ending on 23 March 2000; or

 (ii) beginning on 1 July 2003 and ending on the commencement of this subregulation; and

 (b) the following provisions applied to the application:

 (i) paragraph (c) or (d) of item 2 of Part 2 of Schedule 9;

 (ii) item 4 of Part 2 of Schedule 9; and

 (c) the fee prescribed in paragraph (c) or (d) of item 2 of Part 2 of Schedule 9 for making the application was not paid; and

 (d) the therapeutic good was included in the Register because of the application.

43AA Fee for evaluation — refund in certain circumstances

 If:

 (a) an applicant has paid the whole of the evaluation fee payable under 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 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.

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

 (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.

 (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:

 (i) contain the same active ingredient; or

 (ii) are therapeutic devices;

 (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.

 (3) The Secretary may waive or reduce the application and evaluation fees specified in Schedule 9 that are payable in relation to therapeutic goods if:

 (a) the goods were approved for importation and supply by the Secretary under the Customs (Prohibited Imports) Regulations not earlier than 2 years before the commencement of the Act and supply of those goods has not commenced; or

 (b) the goods were registered by the Health Department of the State of Victoria under the *Health Act 1958* of that State not earlier than 2 years before the commencement of the Act and supply of those goods has not commenced; or

 (c) the goods were accepted for evaluation by the Secretary or the Health Department of the State of Victoria before the commencement of the Act.

 (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

 (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.

 (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.

 (4A) If the Secretary reduces the amount of the evaluation fee payable on an application to register a therapeutic device included in Part 1 of Schedule 3, the amount of the reduced fee payable:

 (a) for an application involving the evaluation of:

 (i) design; or

 (ii) materials information; or

 (iii) testing;

 is $9 580;

 (b) for an application involving the evaluation of:

 (i) manufacture; or

 (ii) quality control; or

 (iii) sterile manufacture; or

 (iv) testing information;

 is $7 970;

 (c) in the case of an application involving the evaluation of 1 or both of the following:

 (i) biocompatability;

 (ii) pre‑clinical information;

 is reduced to $7 710; and

 (ca) in the case of an application involving the evaluation of software — is reduced to $7 710;

 (d) for an application involving the evaluation of human clinical information — is $32 100;

 (e) for an application involving the evaluation of a confirmatory review of clinical information — is $7 710; and

 (f) for an application involving confirmatory evaluation of overseas reports or data lodged to support the application ⎯ is $7 710.

 (8) Subregulation (9) applies if:

 (a) more than 1 application to register a therapeutic device is made at the same time; and

 (b) each application is made by the same sponsor; and

 (c) the device to which each application relates is included in Part 1 of Schedule 3; and

 (d) the information provided in support of each application is sufficiently similar to enable evaluation of each device to be undertaken simultaneously; and

 (e) the sponsor pays the total amount of the fee payable under item 6 in Schedule 9 for the principal application.

 (9) The fee for each application to register a therapeutic device (other than the principal application) to which subregulation (8) applies:

 (a) in the case of an application involving the evaluation of any or all of the following:

 (i) design;

 (ii) materials information;

 (iii) testing;

 is reduced to $4 790; and

 (b) in the case of an application involving the evaluation of any or all of the following:

 (i) manufacture;

 (ii) quality control;

 (iii) sterile manufacture;

 (iv) testing information;

 is reduced to $4 790; and

 (c) in the case of an application involving the evaluation of 1 or both of the following:

 (i) biocompatability;

 (ii) pre‑clinical information;

 is reduced to $4 790; and

 (ca) in the case of an application involving the evaluation of software ⎯ is reduced to $4 790; and

 (d) in the case of an application involving the evaluation of human clinical information — is reduced to $4 790; and

 (e) in the case of an application involving confirmatory evaluation of overseas reports or data lodged to support the application ⎯ is reduced to $4 790.

 (10) Subregulation (11) applies if:

 (a) more than 1 application to vary written information in the Register about a therapeutic device is made at the same time; and

 (b) each application is made by the same sponsor; and

 (c) the device to which each application relates is included in Part 1 of Schedule 3; and

 (d) the information provided in support of each application is sufficiently similar to enable evaluation of each device to be undertaken simultaneously; and

 (e) the sponsor pays the total amount of the fee payable under item 7 in Schedule 9 for the principal application.

 (11) The fee for each application to vary written information (other than the principal application) to which subregulation (10) applies:

 (a) in the case of an application involving review of any or all of the following:

 (i) design;

 (ii) materials information;

 (iii) testing;

 is reduced to $1 750; and

 (b) in the case of an application involving review of any or all of the following:

 (i) manufacture;

 (ii) quality control;

 (iii) sterile manufacture;

 (iv) testing information;

 is reduced to $1 750; and

 (c) in the case of an application involving the evaluation of 1 or both of the following:

 (i) biocompatability;

 (ii) pre‑clinical information;

 is reduced to $1 750; and

 (ca) in the case of an application involving the evaluation of software — is reduced to $1 750; and

 (d) in the case of an application involving review of human clinical information — is reduced to $1 750; and

 (e) in the case of an application involving confirmatory evaluation of overseas reports or data lodged to support the application ⎯ is reduced to $1 750.

 (12) The Secretary must waive the following fees:

 (a) a fee that would have been payable, but for this subregulation, for applying to the Secretary under subregulation 16I (1) to have a medicine designated as an orphan drug;

 (b) a fee that would have been payable, but for this subregulation, for the Secretary considering the application under regulation 16J;

 (c) a fee that would have been payable, but for this subregulation, as part of the registration of a designated orphan drug.

45AA Payment of fees in instalments

 (1) Subject to subregulation (7), the Secretary may allow the amount of a fee payable under item 6 or 7 in Schedule 9 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 decides not to register the therapeutic device — when the applicant is notified under subsection 25 (3) of the Act; or

 (iii) if the evaluation is completed — before the therapeutic device is registered.

 (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.

45A Limit on application fees — low value turnover

 If the total amount payable under item 3AB of Schedule 9 for applications to which subparagraph 43AAC (2) (b) (iii) applies reaches $14 000 in a financial year, the applicant is not required to pay any further amounts for applications under that subparagraph in the financial year.

Part 7A Infringement notices

45B Purpose and effect of Part

 (1) For sections 42YJ and 42YK of the Act, Schedule 15 sets up a system of infringement notices as an alternative to prosecution for an alleged offence of strict liability, or to the institution of civil proceedings for an alleged contravention of a civil penalty provision, under the Act.

 (2) Schedule 15 does not:

 (a) require an infringement notice to be issued to a person for an alleged offence or an alleged contravention; or

 (b) affect a person’s liability to prosecution or to the institution of civil proceedings if an infringement notice for the alleged offence or the alleged contravention:

 (i) is not issued to the person; or

 (ii) is issued, but withdrawn;

 (c) prevent the issue of 2 or more infringement notices to a person for an alleged offence of strict liability or an alleged contravention of a civil penalty provision; or

 (d) affect a person’s liability to prosecution or to the institution of civil proceedings if the person does not pay the penalty for the alleged offence or the alleged contravention specified in an infringement notice in accordance with Schedule 15; or

 (e) limit or otherwise affect the penalty that may be imposed by a court on a person for an offence of strict liability or for the contravention of a civil penalty provision.

Part 8 Miscellaneous

46A Delegation under the Act

 (1) For paragraph 57 (1) (c) of the Act, the following appointments are appointments the occupant or holder of which may be a delegate under section 57 of the Act:

 (a) the appointment of National Manager, Therapeutic Goods Administration;

 (b) the secondment of a person employed by a national therapeutic goods regulatory authority of another country to a position in the Therapeutic Goods Administration.

 (2) For paragraph 57 (8) (b) of the Act, the following positions are prescribed:

 (a) Chief Regulatory Officer;

 (b) Principal Medical Adviser.

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:

 (a) an officer of the Department; or

 (b) the National Manager, Therapeutic Goods Administration.

 (1A) However, a delegation for Schedule 15 may be given only:

 (a) to the Assistant Secretary, of a Branch or an Office, of the Therapeutic Goods Administration; or

 (b) to the National Manager, Therapeutic Goods Administration.

 (2) The delegation must be by instrument signed by the Secretary.

(3) Nothing in subregulation (1) affects the Secretary’s power to delegate a power or function of the Secretary under regulation 5Q or subregulation 9 (3).

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.

 (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 medical 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.

48 Review of decisions

 (1) In this regulation:

***decision*** has the same meaning as in the *Administrative Appeals Tribunal Act 1975*.

***initial decision*** means a decision of the Secretary under any of the following provisions:

 (a) subregulation 9 (1);

 (c) subregulation 10A (7);

 (ca) subregulation 10C (3), (4), (5) or (6);

 (d) subregulation 10F (7);

 (da) subregulation 10H (9);

 (e) subregulation 16J (3);

 (f) subregulation 22 (8);

 (g) regulation 45;

 (h) regulation 45AA.

***reviewable decision*** means a decision of the Minister under subregulation (3).

 (1A) The Minister may, by signed instrument, delegate a power or function of the Minister under this regulation to:

 (a) an officer of the Department; or

 (b) the National Manager, Therapeutic Goods Administration.

 (2) A person whose interests are affected by 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.

 (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.

 (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.

 (6) If written notice of the making of an initial decision is given to a person whose interests are affected by the decision, the notice is to include a statement to the effect that a person whose interests are affected by the decision 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.

 (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.

 (8) An application may be made to the Administrative Appeals Tribunal for review of a reviewable decision.

Part 9 Transitional

49 Transitional

 Despite the amendments made by the *Therapeutic Goods Amendment Regulation 2012 (No. )*:

 (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.

Schedule 1 Part 2 does not apply to members of an Australian branch of one of these bodies

(subregulation 4 (2))

| Column 1Item No. | Column 2Body |
| --- | --- |
| 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 |
| 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 1Item No. | Column 2Representation | Column 3Therapeutic goods |
| --- | --- | --- |
| 1 | a representation that is a prohibited representation under Part 1 of Appendix 6 to the Therapeutic Goods Advertising Code | all 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 | all therapeutic goods |
|  |  (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 |  |
| 4 | a representation referred to in subparagraph 7 (1) (e) (i) or (ii) of the Therapeutic Goods Advertising Code | 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 | disinfectants andantiseptics |
|  |  (f) containing a reference to an effect against viruses, except a representation that is approved in writing by the Secretary; or |  |
|  |  (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 referred to in paragraph 7 (2) (a) or (b) of the Therapeutic Goods Advertising Code | vitamins |
| 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 | vitamins and minerals |
|  |  (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 |  |

Part 2 Required representations

| Column 1Item | Column 2Representation | Column 3Therapeutic goods |
| --- | --- | --- |
| 1 | if the advertisement is in the form of a label on the retail container — a statement that: | vitamin preparations for oral ingestion supplied in Australia |
|  |  (a) vitamins can only be of assistance if the dietary vitamin intake is inadequate; or |  |
|  |  (b) vitamin supplements should not replace a balanced diet |  |

Part 3 Vitamins referred to in Item 3 of Part 1 of this Schedule

| Column 1Item | Column 2Substance | Column 3Name |
| --- | --- | --- |
| 1 | Vitamin A | — |
| 2 | Thiamine | Vitamin B1  |
| 3 | Riboflavine | 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 | Cholecalciferol | 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 registered goods

(regulation 10)

Part 1 Therapeutic devices attracting a higher fee, and medicines

| Item No. | Therapeutic goods |
| --- | --- |
| 1 | medicines that: (a) are not mentioned in item 1 in Part 1 of Schedule 4; and (b) are not designated orphan drugs |
| 2 | medicines that: (a) are not mentioned in items 3 to 10 (inclusive) in Part 1 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, 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 |
| 3 | therapeutic devices, other than devices of a kind mentioned in Part 2, that are: |
|  |  (g) devices that are: (i)articles incorporating tissues, cells or substances of human origin, other than medical devices incorporating stable derivatives of either human blood or human plasma that act on, or are likely to act on, the human body in a way that is ancillary to the device; or |
|  |  (ii) articles incorporating viable tissues, cells or substances of animal origin |

Part 2 Therapeutic devices attracting a lower fee

| Item No. | Therapeutic goods |
| --- | --- |
| 6 | hospital grade or household grade disinfectants that are claimed to be sterilants, fungicides, sporicides, tuberculocides or virucides |

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)

Part 1 Listable goods

| Item No. | Therapeutic goods |
| --- | --- |
| 1 | therapeutic goods manufactured in Australia for export only other than goods exempt under regulation 12 |
| 2 | therapeutic devices other than devices to which: (a) item 3 (g) of Part 1 of Schedule 3 applies; or (aa) Part 2 of Schedule 3 applies; or (b) item 1, 2, 3, 4, 7 or 11 of Schedule 5 applies; or (c) item 1, 1A, 3, 4, 5, 7, 8, 9, 10, 11 or 12 of Schedule 5A applies |
| 3 | preparations containing as their therapeutically active ingredients only vitamins, minerals, herbal substances, a substance mentioned in Part 5 of this Schedule or a combination of those substances where: (a) the preparation: (i) is not included in a Schedule to the Poisons Standard or Appendix C of the Poisons Standard; and (ii) is not of a kind required to be sterile; and (b) the vitamins consist only of vitamins or their salts specified in Part 2 of this Schedule; and (c) the minerals consist only of minerals or their salts specified in Part 3 of this Schedule; and (d) the preparation: (i) does not include a herbal substance derived from plant material mentioned in Division 1 of Part 4 of this Schedule; and (ii) if it contains a herbal substance derived from plant material mentioned in an item in the table in Division 2 of that Part — is consistent with the qualification mentioned in column 3 of that item; and |
|  |  (A) does not include the substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1 mg of the dry herbal starting material; or (B) is not inconsistent with the qualification mentioned, in relation to the substance, in column 3 of the table in that Division; and (e) the herbal substance is present in therapeutic goods included in the Register for supply in Australia;  |
|  |  (f) if a substance mentioned in Division 2 of Part 5 is an ingredient — the preparation is not supplied: |
|  |  (i) in a form that contains the substance in excess of the maximum amount per dosage for that form, as mentioned in column 3 of the table in that Division; and (ii) without the information about daily dosage mentioned in column 4 of the table for that substance; and |
|  |  (g) if a substance mentioned in Division 3 of Part 5 is an ingredient — the preparation is supplied: (i) in accordance with the qualification (if any) mentioned in relation to the substance in that Division; and (ii) with a label that complies with the requirements of the Required Advisory Statements for Medicine Labels for that substance;  |
|  | unless the indications proposed by the sponsor of the preparation are in the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Therapeutic Goods Advertising Code  |
| 4 | mother tinctures |
| 4A | homoeopathic preparations that: (a) consist of, or contain a dilution of, mother tincture that: (i) is a 1,000‑fold dilution, or a lesser dilution, of that mother tincture; and (ii) is not required to be sterile; and (iii) is not included in a Schedule to the Poisons Standard or Appendix C of the Poisons Standard otherwise than because of a component that is more than a 1,000‑fold dilution of a mother tincture; and |
|  |  (b) do not consist of, or contain as a component, a preparation of a herb specified in Part 4 of this Schedule as a 1,000‑fold dilution, or a lesser dilution, of a mother tincture |
| 5 | homoeopathic preparations (where each dilution is more dilute than a one thousand fold dilution of a mother tincture), each of which: (a) is not required to be sterile; and (b) according to the indications proposed by the sponsor of the preparation, is for the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Therapeutic Goods Advertising Code |
| 6 | medicated throat lozenges where the medication consists only of volatile oils and their constituents alone or in combination with ascorbic acid or its salts and unless the indications proposed by the sponsor of the lozenges are in the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Therapeutic Goods Advertising Code |
| 7 | sunscreen preparations for dermal application (other than preparations for the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Therapeutic Goods Advertising Code), 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 sun protection factor stated on the label is: (i) 4 or greater; or (ii) less than 4 and the preparations include an ingredient of human origin, or 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) cerebro‑spinal 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; |
| 8 | uncompounded medicine substances packed for retail sale: (a) being substances that comply with a monograph of the British Pharmacopoeia for those substances and that are not included in a Schedule to the Poisons Standard or Appendix C of the Poisons Standard; and (b) where the indications proposed by the sponsor of the substances are not in the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Therapeutic Goods Advertising Code |
| 9 | medicated space sprays where the medication consists only of volatile oils and their constituents |
| 10 | medicines containing amino acids for therapeutic use singly or in combination with other substances unless: (a) the amino acids are tryptophan, arginine, D‑ or D,L‑phenylalanine, D‑ or D,L‑methionine, D‑ or D,L‑carnitine,D‑ or D,L‑glutamic acid or the salts (except the hydrochloride, monoammonium, calcium, magnesium, monosodium and monopotassium salts) of L‑glutamic acid; or (b) the other substances are included in Schedule 3; or (c) the goods are included in a Schedule to the Poisons Standard or Appendix C of the Poisons Standard; or (d) the goods are in a form required to be sterile; or (e) the indications proposed by the sponsor of the goods are in the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Therapeutic Goods Advertising Code |
| 10A | medicines containing L‑arginine singly or in combination with other substances and intended for application to the skin for a localised effect, if a warning label is attached to the medicine stating that the medicine is to be applied only to the skin, and not to the mucosa, vagina or rectum, unless: (a) the medicine also contains an amino acid, other than L‑arginine, mentioned in paragraph (a) of item 10; or (b) the other substances are included in Schedule 3; or |
|  |  (c) the goods are included in a Schedule to the Poisons Standard or Appendix C of the Poisons Standard; or (d) the goods are in a form required to be sterile; or (e) the indications proposed by the sponsor of the goods are in the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Therapeutic Goods Advertising Code |
| 11 | kits (to be known as ***device kits***) consisting: (a) solely of therapeutic devices; or (b) partly of therapeutic devices and partly of medicines;if Part 3‑2 of the Act applies to any of the individual therapeutic goods contained in the kit |
| 12 | kits (to be known as ***medicine kits***) consisting as follows: (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 when used as recommended by the manufacturer on non critical surfaces if no claim is made that the goods are sterilants, fungicides, sporicides, tuberculocides or virucides |

Part 2 Vitamins and their salts to which paragraph (b) of item 3 of Part 1 of this Schedule applies

| Approved Name | Synonym |
| --- | --- |
| Acetomenaphthone |  |
| Ascorbic acid | Vitamin C |
| Ascorbyl palmitate, other than ascorbyl palmitate in an oral preparation the recommended daily dose of which contains more than 100mg of ascorbyl palmitate |  |
| Betacarotene |  |
| Biotin | Vitamin H |
| Calcium ascorbate |  |
| Calcium folinate |  |
| Calcium pantothenate |  |
| Cholecalciferol | Vitamin D3 |
| Cyanocobalamin | Vitamin B12 |
| Ergocalciferol | Vitamin D2 |
| Folic acid  |  |
| Hydroxocobalamin | Vitamin B12 |
| Magnesium ascorbate  |  |
| Nicotinamide  |  |
| Nicotinamide ascorbate  |  |
| Nicotinic acid  |  |
| d‑Panthenol  |  |
| dl‑Panthenol  |  |
| Pantothenic acid | Vitamin B5 |
| Phytomenadione | Vitamin K1 |
| Potassium ascorbate |  |
| Pyridoxal 5 — phosphate |  |
| Pyridoxine hydrochloride | Vitamin B6 |
| Retinyl acetate | Vitamin A acetate |
| Retinyl palmitate | Vitamin A palmitate |
| Riboflavine | Vitamin B2 |
| Riboflavine sodium phosphate  |  |
| Sodium ascorbate  |  |
| Sodium pantothenate  |  |
| Thiamine hydrochloride | Vitamin B1 |
| Thiamine nitrate  |  |
| Thiamine phosphoric acid ester chloride |  |
| d‑alpha‑Tocopherol | Vitamin E |
| dl‑alpha‑Tocopherol  |  |
| Tocopherols concentrate — mixed (high alpha type) |  |
| Tocopherols concentrate — mixed (low alpha type) |  |
| d‑alpha‑Tocopheryl acetate  |  |
| dl‑alpha‑Tocopheryl acetate  |  |
| d‑alpha‑Tocopheryl acid succinate |  |
| dl‑alpha‑Tocopheryl acid succinate  |  |
| Vitamin A |  |

Part 3 Minerals and their salts to which paragraph (c) of Item 3 of Part 1 of this Schedule applies

| Name |
| --- |
| Ammonium iron (III) citrate |
| Borax |
| Borax pentahydrate |
| Boric acid |
| Calcium amino acid chelate as a source of calcium |
| Calcium carbonate |
| Calcium citrate |
| Calcium gluconate |
| Calcium glycerophosphate |
| Calcium hydrogen phosphate |
| Calcium lactate |
| Calcium lactate gluconate |
| Calcium orotate |
| Calcium phosphate |
| Calcium phosphate — monobasic |
| Calcium sodium lactate |
| Calcium succinate |
| Calcium sulfate |
| Chromium (III) chloride |
| Colloidal anhydrous silica, other than colloidal anhydrous silica in a preparation the proposed route of administration of which is by inhalation |
| Copper gluconate |
| Copper (II) oxide |
| Copper (II) sulfate |
| Ferric glycerophosphate |
| Ferric pyrophosphate |
| Ferrous carbonate |
| Ferrous chloride |
| Ferrous fumarate |
| Ferrous gluconate |
| Ferrous lactate |
| Ferrous phosphate |
| Ferrous succinate |
| Ferrous sulfate |
| High selenium yeast |
| Iron amino acid chelate as a source of iron |
| Iron (III) chloride |
| Magnesium amino acid chelate as a source of magnesium |
| Magnesium aspartate |
| Magnesium carbonate |
| Magnesium chloride |
| Magnesium citrate |
| Magnesium gluconate |
| Magnesium glycerophosphate |
| Magnesium orotate |
| Magnesium oxide |
| Magnesium phosphate |
| Magnesium phosphate dibasic trihydrate |
| Magnesium sulfate |
| Manganese amino acid chelate as a source of manganese |
| Manganese aspartate |
| Manganese chloride |
| Manganese gluconate |
| Manganese glycerophosphate |
| Manganese (IV) oxide |
| Manganese (II) sulfate |
| Molybdenum trioxide |
| Potassium aspartate |
| Potassium citrate |
| Potassium gluconate |
| Potassium glycerophosphate |
| Potassium iodide |
| Potassium orotate |
| Potassium phosphate |
| Potassium sulfate |
| Selenocysteine |
| Selenomethionine |
| Silicon dioxide, other than silicon dioxide in a preparation the proposed route of administration of which is by inhalation |
| Sodium chloride |
| Sodium glycerophosphate |
| Sodium perborate |
| Sodium phosphate |
| Sodium selenate |
| Sodium selenite |
| Sodium sulfate |
| Zinc amino acid chelate as a source of zinc |
| Zinc ascorbate |
| Zinc chloride |
| Zinc citrate |
| Zinc gluconate |
| Zinc oxide |
| Zinc succinate |
| Zinc sulfate |

Part 4 Herbal substances to which paragraph (d) of item 3 of Part 1 of this Schedule applies

Division 1 Plant material from which herbal substances in listable goods must not be derived

| Name |  |
| --- | --- |
| *Abrus precatorius* seed and root |  |
| *Acorus calamus* |  |
| *Amanita* (all or any species) |  |
| *Anadenanthera peregrina* |  |
| *Argyreia nervosa* |  |
| *Aristolochia* (all or any species) |  |
| *Aspergillus fumigatus* |  |
| *Aspergillus nidulans* |  |
| *Aspergillus niger* |  |
| *Aspergillus sydowi* |  |
| *Aspergillus terreus* |  |
| *Banisteriopsis caapi* |  |
| *Candida albicans* |  |
| *Cannabis* |  |
| *Catha edulis* |  |
| *Conocybe* (all or any species) |  |
| *Crotalaria* (all or any species) |  |
| *Cynoglossum officinale* |  |
| *Epidermophyton floccosum* |  |
| *Erythroxylum coca* |  |
| *Geotrichum candidum* |  |
| *Gymnopilus* (all or any species) |  |
| *Haemadictyon* (all or any species)  |  |
| *Heliotropium* (all or any species) |  |
| *Ipomoea burmanni (Rivea corymbosa)* |  |
| *Ipomoea hederacea*  |  |
| *Ipomoea violacea (Ipomoea tricolor)* |  |
| *Lophophora* (all or any species) |  |
| *Microsporum audouinni* |  |
| *Microsporum canis* |  |
| *Opuntia cylindrica* |  |
| *Papaver bracteatum* |  |
| *Papaver somniferum* |  |
| *Peganum harmala* |  |
| *Petasites* (all or any species) |  |
| *Piptadenia macrocarpa*  |  |
| *Piptadenia peregrina* |  |
| *Psylocybe* (all or any species)  |  |
| *Pteridium aquilinum* |  |
| *Rhizopus oligosporus* |  |
| *Senecio* (all or any species) |  |
| *Sophora secundiflora* |  |
| *Stropharia cubensis*  |  |
| *Strychnos gaulthieriana* |  |
| *Strychnos ignatii (Ignatia amara)* |  |
| *Symphytum* (all or any species) |  |
| *Trichophyton* (all or any species) |  |
| *Tussilago farfara* |  |
| *Virola sebifera* |  |

*Note*   As to preparations containing a herbal substance derived from a herb not approved in Australia for therapeutic use in humans, *see* Schedule 3, item 2.

Division 2 Plant material from which herbal substances may be derived for listable goods that are consistent with certain qualifications

| Item | Plant material | Qualification |
| --- | --- | --- |
| 1 | *Abrus cantoniensis* | if the herbal substance is derived from the seed — the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry seed |
| 2 | *Arisaema* (all or any species)  | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 3 | *Armoracia rusticana (Cochlearia armoracia)* | the preparation does not contain, for its recommended daily dose, more than 20mg of volatile oil components |
| 4 | *Arnica* (all or any species) | if the preparation is for any use other than external use — it does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 5 | *Arum maculatum* | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 5A | *Azadirachta indica (Neem)* |  (a) the herbal substance is derived from the seed in the form of cold pressed oil; and |
|  |  |  (b) the proposed route of administration of the preparation containing the herbal substance is topical; and (c) if the preparation contains more than 1% of the herbal substance: (i) the preparation is provided in a container fitted with a child‑resistant closure; and (ii) label on the goods complies with the requirements of the Required Advisory Statements for Medicine Labels |
| 6 | *Backhousia citriodora* |  (a) the herbal substance is derived from leaf oil only; and (b) the proposed route of administration of the preparation is topical only; and (c) the concentration of the herbal substance does not exceed 10mg per g of the preparation; and |
|  |  |  (d) the label on the goods complies with the requirements of the Required Advisory Statements for Medicine Labels |
| 7 | *Brachyglottis* (all or any species) | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 8 | *Brassica* (all or any species) | if the herbal substance is derived from the seed — the preparation does not contain, for its recommended daily dose, more than 20mg of allyl isothiocyanate (volatile oil component) |
| 9 | *Brunfelsia uniflora* | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 10 | *Chenopodium ambrosioides* | the preparation does not contain, for its recommended daily dose, more than 10mg of volatile oil components |
| 11 | *Cicuta virosa* | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 12 | *Croton* (all or any species) | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 13 | *Daphne mezereum* | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 14 | *Dryopteris filix‑mas* | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 15 | *Echium vulgare* | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 16 | *Euonymus europaeus* | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 17 | *Helleborus* (all or any species) | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 18 | *Hirschfeldia incana* | if the herbal substance is derived from the seed — the preparation does not contain, for its recommended daily dose, more than 20mg of allyl isothiocyanate (volatile oil component) |
| 19 | *Hydnocarpus anthelmintica* | if the herbal substance is derived from the seed or seed oil and the preparation is for any use other than external use — the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry seed |
| 20 | *Hypericum perforatum* | if the preparation is not a homoeopathic preparation and the proposed route of administration of the preparation is oral — the label on the goods complies with the requirements of the Required Advisory Statements for Medicine Labels |
| 21 | *Kunzea ambigua* |  (a) the herbal substance is derived from essential oils only; and (b) the proposed route of administration of the preparation is topical or by inhalation of the vapour only; and (c) the preparation is supplied in a container with a restrictive flow insert; and |
|  |  |  (d) the label on the goods complies with the requirements of the Required Advisory Statements for Medicine Labels |
| 22 | *Lantana camara* | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 23 | *Lathyrus sativus* | if the preparation contains lathyrogenic amino acids — it does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 24 | *Lithospermum* (all or any species) | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 25 | *Lycopersicon esculentum* | if the preparation is for any use other than external use — it does not contain, for its recommended daily dose, more than 10mg of total steroidal alkaloids |
| 26 | *Medicago sativa* | the L‑canavanine level is not more than that of the dried leaf of the plant |
| 27 | *Menispermum canadense* | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 28 | *Mentha pulegium* |  (a) if the preparation is for external use — it does not contain, for its recommended daily dose, more than 150mg of volatile oil components; and (b) if the preparation is for any other use — it does not contain, for its recommended daily dose, more than 50mg of volatile oil components |
| 29 | *Monstera deliciosa* | if the herbal substance is derived from the leaf — the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry leaf |
| 30 | *Morinda citrifolia* | the herbal substance is fruit juice only |
| 31 | *Oenanthe* (all or any species) | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 32 | *Paullinia cupana* | the label on the goods complies with the requirements of the Required Advisory Statements for Medicine Labels |
| 33 | *Peumus boldus* | the preparation does not contain, for its recommended daily dose, more than 100mg of volatile oil components |
| 34 | *Phytolacca decandra (americana)* | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 35 | *Piper methysticum* |  (a) if the herbal substance is for oral use: (i) it is any of the following: (A) aqueous dispersion of whole or peeled rhizome; (B) aqueous extract of whole or peeled rhizome; |
|  |  |  (C) dried whole or peeled rhizome; and (ii) the preparation does not contain, for its recommended daily dose, more than 250mg of kavalactones; and (iii) if the preparation is in the form of a tablet or capsule — the amount of kavalactones does not exceed 125mg for each tablet or capsule; and (iv) if the preparation is in the form of a tea bag — the amount of dried whole or peeled rhizome does not exceed 3g for each tea bag; and |
|  |  |  (v) if the preparation contains more than 25mg of kavalactones per dose — the label on the goods complies with the requirements of the Required Advisory Statements for Medicine Labels; |
|  |  |  (b) if the herbal substance is for topical application to the rectum or vagina or by spray to the throat — it is any of the following: (i) aqueous dispersion of whole or peeled rhizome; (ii) aqueous extract of whole or peeled rhizome; (iii) dried whole or peeled rhizome; |
|  |  |  (c) if the herbal substance is not a substance to which paragraph (a) or (b) applies, the herbal substance may be: (i) used in homeopathic preparations more dilute than a 1 000‑fold dilution of a mother tincture; or |
|  |  |  (ii) used in a preparation for topical application to the skin if the preparation does not contain, for its daily dose, more than 250mg of kavalactones |
| 36 | *Prunus dulcis (P. amygdalus)* var*. amara* | if the herbal substance is derived from the seed — the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry seed |
| 37 | *Pseudolarix kaempferi* | if the herbal substance is derived from plant parts other than the stem, bark or root, or if the preparation is for any use other than external use — the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 38 | *Pseudowintera colorata* | the herbal substance is derived from the leaf only |
| 39 | *Rhododendron molle* | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 40 | *Ricinus communis*  | the herbal substance is the fixed oil of the seed only |
| 41 | *Robinia pseudoacacia* | if the herbal substance is derived from plant parts other than the leaf or flower — the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 42 | *Rohdea japonica*  | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 43 | *Santalum spicatum* |  (a) the herbal substance is oil derived from the root or stem wood only; and (b) the proposed route of administration of the preparation is topical or by inhalation only |
| 44 | *Schoenocaulon officinale (Sabadilla officinarum, Veratrum officinale)* | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 45 | *Semecarpus anacardium (Anacardium orientale)* | if the herbal substance is derived from plant parts other than the seed — the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 46 | *Sinapsis alba* | if the herbal substance is derived from the seed — the preparation does not contain, for its recommended daily dose, more than 20mg of allyl isothiocyanate (volatile oil component) |
| 47 | *Solanum* (all or any species) | if the preparation is for any use other than external use — it does not contain, for its recommended daily dose, more than 10mg of total steroidal alkaloids including solanine, solaneine and solanidine |
| 48 | *Spigelia marilandica* | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 49 | *Tamus communis* | if the herbal substance is derived from the fruit or root — the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 49A | *Terminalia ferdinandiana* | the preparation contains only aqueous extracts of the fruit flesh or fruit flesh dry |
| 50 | *Teucrium* (all or any species) | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 51 | *Toxicodendron radicans (Rhus toxicodendron)* | the preparation does not contain the herbal substance in a quantity that exceeds, for the recommended daily dose of the preparation, the equivalent of 1mg of the dry herbal material |
| 52 | *Trametes versicolor* | the preparation only contains aqueous extracts of the hyphae, dried to powder form |

Part 5 Substances specified for item 3 of Part 1

Division 1 Substances, not mentioned in Division 2 or 3, that may be ingredients of preparations

|  |
| --- |
| Acetyllevocarnitine hydrochloride |
| Alfalfa (*Medicago sativa*) — fresh leaf extract, having a concentration ratio between 34:1 and 46:1 and L‑canavanine level not more than fresh alfalfa leafBacterial strains from the genera Lactobacillus and Bifidobacterium, other than strains of *Lactobacillus catenaformis*, *Lactobacillus uli* and *Bifidobacterium dentium* |
| Beta‑hydroxy‑beta‑methylbutyric acid  |
| Black boned chicken powder |
| Bromelains |
| Calcium beta‑hydroxy‑beta‑methylbutyrate |
| Calcium hydroxycitrate |
| Chitosan |
| Chlorophyll |
| Choline bitartrate |
| Chondroitin sulfate — bovine |
| Chondroitin sulfate — shark |
| Citrus bioflavonoids extract |
| Conifer phytosterol complex |
| Demineralised fish proteoglycan extract |
| Dolomite |
| Emu oil |
| Fish oils |
| Fructose |
| Glucosamine hydrochloride |
| Glucosamine sulfate potassium chloride complex |
| Glucosamine sulfate sodium chloride complex |
| Glucosamine sulphate |
| Glucose |
| Honey (except honey intended to be administered orally) |
| Hydroxyapatite |
| Hydroxycitric acid |
| Inositol |
| Inulin |
| Lecithin |
| Levocarnitine |
| Levocarnitine fumarate |
| Levocarnitine hydrochloride |
| Levocarnitine magnesium citrate |
| Levocarnitine tartrate |
| Lutein |
| Lycopene |
| Methylcellulose |
| Oligofructose |
| Oyster shell |
| Papain |
| Pectin |
| Phosphatidylserine‑enriched soy lecithin |
| Potassium hydroxycitrate |
| Propionyllevocarnitine hydrochloride |
| Propolis |
| Quercetin |
| R‑alpha lipoic acid |
| R, S‑alpha lipoic acid |
| Rice — hydrolysed |
| Royal jelly |
| Shark cartilage |
| Sodium beta‑hydroxy‑beta‑methylbutyrate |
| Sodium hydroxycitrate |
| Squalene |
| Starch — maize — high amylose |
| *Streptococcus thermophilis* |
| Tocotrienols complex — palm |
| Zeaxanthin |

Division 2 Substances subject to dosage limit

**Subdivision 1 Interpretation**

1. A reference in column 3 of the table to a maximum amount per dosage form in relation to a substance mentioned in column 2 is a reference to the maximum amount of the substance that can be present in the particular dosage form mentioned in column 3 in relation to a preparation containing the substance.

2. A reference in column 4 of the table to a maximum daily dose in relation to a substance mentioned in column 2 is a reference to the daily maximum intake of the substance, in all dosage forms containing the substance.

3. A reference in this Division to a dosage form of a substance mentioned in column 2 of the table:

 (a) is a reference to the form in which a preparation containing the substance is sold, or otherwise distributed (for example, as a tablet or capsule); and

 (b) is not a reference to other chemical compounds in which the substance mentioned in column 2 may occur.

 *Example*

For example, a preparation including chromium nicotinate (a substance mentioned in column 2 of the table) that contains 50 micrograms of chromium complies with the dosage limitation even though it also contains any of the mineral salts mentioned elsewhere in this Schedule.

**Subdivision 2 Maximum amounts and daily doses of specified substances**

| Item | Substance | Maximum amount per dosage form | Maximum daily dose (all dosage forms) |
| --- | --- | --- | --- |
| 1A | Borax |  | 3 mg of boron |
| 1B | Borax pentahydrate |  | 3 mg of boron |
| 1C | Boric acid |  | 3 mg of boron |
| 1 | Chromium nicotinate |  | 50 g of chromium  |
| 2 | Chromium picolinate |  | 50 g of chromium |
| 3 | High chromium yeast |  | 50 g of chromium |
| 4 | Cupric citrate |  | 750 g of copper |
| 4A | Molybdenum trioxide |  | 125 g of molybdenum |
| 5 | High molybdenum yeast |  | 62.5 g of molybdenum |
| 6 | Sodium perborate |  | 3 mg of boron |
| 7 | Sugar cane wax alcohols |  | 12 mg |
| 8 | Ubidecarenone |  | 150 mg |

*Note*   Certain substances mentioned in this Division are also mentioned in Division 3.

Division 3 Substances requiring a label with an advisory statement

 1. Activated charcoal.

 2. Ademetionine in the form of sulphate salts, tosylate salts or mixed sulphate and tosylate salts.

 3. Bovine colostrum powder.

 4. Bovine lactoferrin.

 5. Calcium sodium caseinate.

 6. Creatine.

 7. Creatine monohydrate.

 8. Creatine phosphate.

 9. Honey (for oral administration).

 10. (*S*)‑S‑Adenosylmethionine in the form of sulphate salts, tosylate salts or mixed sulphate and tosylate salts.

 11. Selenium yeast — high.

 12. Selenocysteine.

 13. Selenomethionine.

 14. Sodium selenate.

 15. Sodium selenite.

 16. Sodium sulfate, other than sodium sulfate intended for laxative use.

 17. Sugar cane wax alcohols.

 18. Ubidecarenone.

Schedule 5 Therapeutic goods exempt from the operation of Parts 3-2 and 3-2A of the Act

(subregulation 12 (1))

| Column 1Item No. | Column 2Therapeutic 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 (b) for injections that contain material of human or animal origin — the goods are the subject of an approval under section 19 of the Act, or are insulin preparations; 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 the control of the Customs and that are not subject to manufacture in Australia |
| 6 | medicines (other than medicines used for gene therapy) that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person |
| 7 | manufacturing, laboratory and dispensary equipment used in the preparation of therapeutic goods |
| 8 | the following medicines unless the indications proposed by the sponsor are in the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Therapeutic Goods Advertising Code: (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; (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; (b) antiperspirant preparations that derive their antiperspirant properties from inorganic salts of aluminium, zinc or zirconium only; (c) unmedicated anti‑acne preparations having only a cleansing action or purpose; (d) medicated insect repellants 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; |
|  |  (e) lotions, shampoos or hairdressings for the prevention or treatment of dandruff except those that are included in a Schedule to the Poisons Standard; |
|  |  (f) disinfectants, except: (i) disinfectants included in item 6 of Part 2 of Schedule 3; or (ii) disinfectants included in item 16 of Part 1 of 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; |
| 9 | medicines or biologicals that are starting materials used 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 |

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 1Item | Column 2Therapeutic goods | Column 3Conditions |
| --- | --- | --- |
| 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) or 32CK (1) of the Act; or (c) authorised for supply under subsection 19 (5) or 32CM (1) of the Act; or (d) dispensed as a medicine or biological prescribed for a Category A patient within the meaning of subregulation 12A (5) |  (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 (c) if the goods are not used within 12 months of importation: (i) in the case of therapeutic goods other than therapeutic devices and biologicals — the goods must be destroyed within 1 month of the end of that period; and (ii) in the case of therapeutic devices or biologicals — the devices or biologicals must be destroyed or returned to the consignor of the devices or biologicals within 1 month of the end of that period; and |
|  |  |  (d) the sponsor must: |
|  |  |  (i) keep records relating to the source and supply of the goods; and |
|  |  |  (ii) if the goods are destroyed under paragraph (c), keep records relating to the destruction; 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, 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 — supply 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 therapeutic devices and biologicals — the goods must be destroyed; or |
|  |  |  (ii) in the case of therapeutic devices or biologicals — the devices or biologicals must be destroyed or returned to the consignor of the devices or biologicals within 1 month of the decision not to register, list or include the devices or biologicals |
| 3 | Therapeutic goods used solely for experimental purposes in humans |  (a) before starting to use the goods, 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;that the sponsor intends to sponsor a clinical trial using specified goods; and (b) the notification must be accompanied by the relevant notification fee referred to in item 14 or 14A of Schedule 9 or item 17 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 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 |
| 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 therapeutic device or 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, other than goods referred to in item 3 or biologicals, that are:  (a) manufactured by a person: (i) under a contract between the person and a private hospital; and (ii) in accordance with a formulation specified by the private hospital; and (iii) for use by, or in connection with, a patient of the private hospital; or |  (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 |
|  |  (b) manufactured by a person: (i) under a contract between the person and a public hospital in a State or Territory; and (ii) in accordance with a formulation specified by the public hospital; and (iii) for use by, or in connection with, a patient of a public hospital in the same State or Territory; or |  (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 private hospital, public hospital or public institution that entered the contract |
|  |  (c) manufactured by a person: (i) under a contract between the person and a public institution; and (ii) in accordance with a formulation specified by the public institution; and (iii) for use by, or in connection with, a patient of the public institution  |  |
| 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 therapeutic device or 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 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 therapeutic device or 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, 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 therapeutic device or 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 |
|  |  |  (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 therapeutic device or 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. |

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 or authority under section 19, 32CK or 32CM of the Act is given; 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 6 Therapeutic devices prescribed for the purposes of paragraph 26 (1) (g) of the Act

(regulation 16)

| Column 1Item No. | Column 2Device |
| --- | --- |
| 1 | therapeutic devices supplied as pharmaceutical benefits |
| 2 | therapeutic devices that are required to be, or that are represented to be, sterile |

Schedule 7 Therapeutic goods exempt from the operation of Part 3‑3 of the Act unless supplied as pharmaceutical benefits

(regulation 17)

| Column 1Item No.  | Column 2Therapeutic 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 licensed manufacturers |
| 3 | therapeutic devices that are not sterile and do not contain or include any sterile component or portion, other than devices mentioned in paragraph (g) of item 3 in Part 1 of Schedule 3 |
| 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 |
| 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 |
| 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 |

Schedule 8 Persons exempt from the operation of Part 3‑3 of the Act

(regulation 18)

| Column 1Item | Column 2Persons | Column 3Matter 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) a medicine by a medical practitioner or a dentist specifically for a patient under his or her care; or (b) a therapeutic device by a health care worker specifically for a patient under his or her care |
| 2 | pharmacists | the manufacture of therapeutic goods, other than biologicals, produced by the pharmacist: (a) in a pharmacy where the pharmacist practices and the pharmacy is open to the public; or (b) on the premises of a dispensary conducted by a Friendly Society; or (c) on the premises of a private hospital;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 requirements of the Standard for the Uniform Scheduling of Drugs and Poisons (commonly known as “the Poisons Standard”) | the application of the new label |

Schedule 9 Fees — therapeutic goods other than biologicals

(regulation 43)

Part 1 Interpretation of table

1 Definitions

 (1) In this table:

***broadcast media*** has the meaning given by section 42B of the Act.

***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 (***previously registered medicine***):

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

 (b) has the same pharmaceutical form; and

 (c) is bioequivalent; and

 (d) has the same safety and efficacy properties.

***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.

***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.

***regional area*** means an area in a State or Territory other than the metropolitan area of the capital city of that State or Territory.

***regional station*** means a radio station or television station that delivers radio programs or television programs to persons in a regional area only.

***specified media*** has the meaning given by section 42B of the Act.

 (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.

Part 2 Table of fees

| Column 1Item | Column 2Matter | Column 3Fee $ |
| --- | --- | --- |
| 1A | Application fee for processing an application for consent under section 14 of the Act  | 410 |
| 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 | 1 520 |
|  |  (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 |  |
|  |  (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 | 18 900 |
|  |  (c) if the goods are therapeutic devices referred to in item 3 of Part 1 of Schedule 3 for use solely for experimental purposes in humans where clinical studies are conducted to demonstrate safety and effectiveness | 15 900 |
|  |  (d) if the goods are therapeutic devices for use solely for experimental purposes in humans and are goods to which paragraph (c) does not apply | 2 400 |
| 2 | Application fee for the purposes of paragraph 23 (2) (a) of the Act for registration of therapeutic goods (if regulation 43A does not apply and the application is not an application to which item 2AA or 3A applies): |  |
|  |  (a) for an application relating to a medicine to which item 4 does not apply | 1 370 |
|  |  (b) for an application relating to a therapeutic device of a kind mentioned in Part 2 of Schedule 3 | 1 280 |
|  |  (ba) for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (a) of item 4 | 42 000 |
|  |  (bb) for an application relating to a medicine in relation to which an evaluation fee is payable under subparagraph (aa) (i) or (ii) of item 4 | 14 000 |
|  |  (bc) for an application relating to a medicine in relation to which an evaluation fee is payable under subparagraph (aa) (iii) of item 4 | 28 000 |
|  |  (bd) for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (b) of item 4  | 25 000 |
|  |  (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  (ii) a major variation | 8 3305 430 |
|  |  (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 (ii) a major variation | 16 70010 900 |
|  |  (bg) for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (c) of item 4  | 16 100 |
|  |  (bh) for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (d) of item 4  | 2 640 |
|  |  (bi) for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (g) of item 4  | 16 300 |
|  |  (bj) for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (h) of item 4  | 960 |
|  |  (c) subject to paragraph (d), for an application in any other case (d) subject to paragraph (f), 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 or are therapeutic devices; 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 | 3 8201 910 — for each additional application, up to a maximum amount payable of 11 100 (including the fee payable under paragraph (c)) |
|  |  (f) if a person submits at the same time more than one application relating to item 5 and: (i) each of which relates to goods that contain the same therapeutically active ingredient; and (ii) the information in support of each of which is sufficiently common in respect of the goods to enable a simultaneous evaluation of the goods to be made; for each additional application | 600 |
|  |  (g) if: (i) a person submits at the same time more than 1 application relating to item 7; and (ii) the information in support of the applications is sufficiently common in respect of the therapeutic devices to which they relate to enable simultaneous evaluation of the devices; for each additional application | 1 280 |
|  | (h) if: (i) a person submits at the same time more than 1 application for a therapeutic device of a kind mentioned in Part 2 of Schedule 3; and (ii) the information in support of the application for each device is sufficiently common to enable simultaneous evaluation of each of the devices; for each additional application | 640 |
| 2AA | Application fee for the purposes of paragraph 23 (2) (a) of the Act for the registration of therapeutic goods if the previous registration was cancelled solely because of failure to pay the annual registration charge and the application is made within 30 days of the cancellation | 580 |
| 2A | Fee for varying an entry in the Register (not including evaluation of data) under section 9D of the Act, if the variation is for: |  |
|  |  (a) a registered medicine that is mentioned in Part 1 of Schedule 10 — for each submission | 1 480 |
|  |  (b) a registered medicine that is mentioned in Part 2 or Part 3 of Schedule 10 | 1 370 |
|  |  (c) a listed medicine | 360 |
|  |  (d) a registered therapeutic device that is mentioned in Part 2 of Schedule 3 | 390 |
|  |  (e) a registered therapeutic device, other than a device mentioned in paragraph (d) | 390 |
|  |  (f) a listed therapeutic device | 390 |
|  |  (g) a medical device | 390 |
| 2AB | Application fee for the variation of entry of a kind of IVD medical device in the Register because the entry contains incomplete or incorrect information | 370 |
| 2AC | Application fee for an application under subsection 9D (3) of the Act to which regulation 16D applies | 960 |
| 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 | 4 790 |
| 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 | 3 830 |
| 2CA | Evaluation fee in relation to an application under subsection 9D (2) of the Act, for the evaluation of data — for each submission | 4 790 |
| 3 | Application fee for paragraph 23 (2) (a) of the Act for the listing of therapeutic goods (other than for an application to which regulation 43A, or item 3AA applies) if the goods are: |  |
|  |  (a) a device | 390 |
|  |  (b) a medicine | 720 |
| 3AA | Application fee for the purposes of paragraph 23 (2) (a) of the Act for the listing of therapeutic goods if the previous listing was cancelled solely because of failure to pay the annual listing charge and the application is made within 30 days of the cancellation | 580 |
| 3A | Application fee for paragraph 23 (2) (a) of the Act for registration of a therapeutic device to which item 5 of Part 1 of Schedule 3 applies (if the application is not an application to which item 2AA applies) | The fee applicable under paragraph 2 (c) or (d) for an application of that nature |
| 3AB | Fee for an application for exemption under subparagraph 43AAC (2) (b) (iii) for a new entry or an existing entry | 140 |
| 3B | Evaluation fee for subsection 24 (1) of the Act for a therapeutic device to which item 5 of Part 1 of Schedule 3 applies, if the evaluation is for: |  |
|  |  (a) the device | The fee applicable under item 6 for an evaluation of that nature |
|  |  (b) a document setting out animal toxicological information about the medicinal component of the device | The fee applicable under item 4 for an evaluation of that nature |
|  |  (c) a document setting out the chemistry, quality control and manufacturing information of the medicinal component of the device | The fee applicable under item 4 for an evaluation of that nature |
| 4 | Evaluation fee, for subsection 24 (1) of the Act, under a submission for evaluation relating to: |  |
|  |  (a) a new chemical entity (other than an entity to which paragraph (aa) applies) | 168 100 |
|  |  (aa) a new chemical entity incorporated as an ancillary medicinal component of a medical device or a therapeutic device if the evaluation of the new chemical entity involves an evaluation of: |  |
|  |  (i) documentation setting out the chemistry, quality control and manufacturing of the new chemical entity; or | 56 100 |
|  |  (ii) documentation relating to pre‑clinical studies; or | 56 100 |
|  |  (iii) documentation mentioned in subparagraphs (i) and (ii) | 112 000 |
|  |  (b) an extension of indications (other than an extension of indications to which paragraph (bb) applies) (bb) an extension of indications or a major variation in respect of a medicine incorporated as an ancillary medicinal component of a medical device or a therapeutic device if the evaluation of the medicine involves an evaluation of: | 99 900 |
|  |  (i) documentation setting out the chemistry, quality control and manufacturing of the medicine; or | for an evaluation relating to:(a) an extension of indications — 33 300(b) a major variation — 21 600 |
|  |  (ii) documentation relating to pre‑clinical studies; or | for an evaluation relating to:(a) an extension of indications — 33 300(b) a major variation — 21 600 |
|  |  (iii) documentation mentioned in subparagraphs (i) and (ii) | for an evaluation relating to:(a) an extension of indications — 66 600(b) a major variation — 43 400 |
|  |  (c) a new generic product | 64 100 |
|  |  (d) an additional trade name | 10 600 |
|  |  (g) a major variation (that is not a variation mentioned in any of paragraphs (a) to (d)) | 65 000 |
|  |  (h) a minor variation (that is not a variation mentioned in any of paragraphs (a) to (d)) | 3 830 |
| 5 | Evaluation fee: (a) under subsection 24 (1) of the Act — in respect of a medicine to which item 4 does not apply, if the evaluation documentation does not contain clinical or toxicological information (b) under subsection 24 (1) of the Act — in respect of a medicine to which item 4 does not apply, if the evaluation documentation contains clinical or toxicological information, and the total number of pages is: | 9 170 |
|  |  (i) not over 50 pages | 9 170 |
|  |  (ii) over 50 pages, but not over 250 pages | 11 800 |
|  |  (iii) over 250 pages, but not over 500 pages | 16 100 |
|  |  (iv) over 500 pages, but not over 1 000 pages | 21 400 |
|  |  (v) over 1 000 pages, but not over 2 000 pages | 32 100 |
|  |  (vi) over 2 000 pages, but not over 3 000 pages | 42 800 |
|  |  (vii) over 3 000 pages | 64 100 |
|  |  (c) under subsection 9D (1), (2) or (3) of the Act ⎯ in relation to an entry in the Register relating to a medicine (other than an entry for goods in relation to which a fee specified in item 4 applies), if the evaluation documentation does not contain clinical or toxicological information | 3 310 |
|  |  (d) under subsection 9D (1), (2) or (3) of the Act — in relation to an entry in the Register relating to a medicine (other than an entry for goods in relation to which a fee specified in item 4 applies), if the evaluation documentation contains clinical or toxicological information, and the total number of pages is: |  |
|  |  (i) not over 50 pages | 3 310 |
|  |  (ii) over 50 pages, but not over 250 pages | 11 800 |
|  |  (iii) over 250 pages, but not over 500 pages | 16 100 |
|  |  (iv) over 500 pages, but not over 1 000 pages | 21 400 |
|  |  (v) over 1 000 pages, but not over 2 000 pages | 32 100 |
|  |  (vi) over 2 000 pages, but not over 3 000 pages | 42 800 |
|  |  (vii) over 3 000 pages | 64 100 |
| 5A | Evaluation fee for subsection 24 (1) of the Act for a therapeutic device to which any of items 2 to 5 of Part 2 of Schedule 3 applies, and that involves the evaluation of: |  |
|  |  (a) design or materials information or testing | 4 790 |
|  |  (b) manufacture, quality control or sterile manufacture, or testing information | 4 790 |
|  |  (c) biocompatability or pre‑clinical information | 4 790 |
|  |  (d) software | 4 790 |
|  |  (e) human clinical information | 4 790 |
|  |  (f) control material for use with diagnostic goods for *in vitro* use | 4 790 |
| 5B | Evaluation fee for subsection 24 (1) of the Act in respect of disinfectants or diagnostic goods for *in vitro* use | 15 900 |
| 6 | Evaluation fee for the purposes of subsection 24 (1) of the Act in respect of a therapeutic device to which any of items 1 to 4 of Part 1 of Schedule 3 applies involving the evaluation of: |  |
|  |  (a) design or materials information or testing | 28 100 |
|  |  (b) manufacture, quality control or sterile manufacture or testing information; | 19 100 |
|  |  (c) biocompatability or pre‑clinical information; | 19 100 |
|  |  (ca) software; | 19 100 |
|  |  (d) human clinical information | 32 100 |
| 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 | 340 |
| 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) | 600 |
| 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 | 1 820 |
| 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) | 1 020 |
| 6AD | Fee for evaluation, under section 25 of the Act, in relation to a therapeutic device: |  |
|  |  (a) establishing from overseas reports or data that the manufacture of the device is of an acceptable standard | 19 100 |
|  |  (b) if a person makes simultaneous applications in relation to more than 1 device and the overseas reports or data in support of the application for each device have sufficient commonality that a simultaneous evaluation of the manufacture of each device may conveniently be made — performing the function mentioned in paragraph (a) in relation to each such additional device | 4 790 |
| 6A | Fee for evaluation of data, under subsection 9D (1), (2) or (3) of the Act, about an entry in the Register relating to a therapeutic device to which any of items 2 to 5 of Part 2 of Schedule 3 applies | 1 280 |
| 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 and diagnostic goods for *in vitro* use | 3 210 |
| 6C | Fee for evaluating documents and other information, relating to the safety of a medicine, obtained under paragraph 31 (2) (f) of the Act (other than an evaluation to which item 6D applies) | 6 980 |
| 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 | 9 170 |
|  |  (b) over 50 pages, but not over 250 pages | 11 800 |
|  |  (c) over 250 pages, but not over 500 pages | 16 100 |
|  |  (d) over 500 pages, but not over 1 000 pages | 21 400 |
|  |  (e) over 1 000 pages, but not over 2 000 pages | 32 100 |
|  |  (f) over 2 000 pages, but not over 3 000 pages | 42 800 |
|  |  (g) over 3 000 pages | 64 100 |
| 7 | Evaluation fee for data submitted in support of a change to a therapeutic device to which any of items 1 to 4 of Part 1 of Schedule 3 applies, if the evaluation involves review of: |  |
|  |  (a) design or materials information or testing | 9 580 |
|  |  (b) manufacturing, quality control and sterile manufacture or testing information; | 7 970 |
|  |  (c) biocompatability or pre‑clinical information; | 7 970 |
|  |  (ca) software; | 7 970 |
|  |  (d) human clinical information | 32 100 |
|  |  (e) confirmatory review of clinical information | 7 970 |
|  |  (f) confirmatory evaluation of overseas reports or data | 7 970 |
| 7AA | Fee for evaluation of data submitted in support of a change to a therapeutic device to which item 5 of Part 1 of Schedule 3 applies, if the evaluation involves review of: |  |
|  |  (a) the device (not including the medicinal component of the device) | The fee applicable under item 7 for an evaluation of that nature |
|  |  (b) the medicinal component of the device | The fee applicable under item 4 and paragraph (d) of item 7 for an evaluation of that nature |
|  |  (c) the device (including the medicinal component of the device) | The fee applicable under items 4 and 7 for an evaluation of that nature |
| 7A | Fee for evaluation under paragraph 16GA (1) (a): |  |
|  |  (a) if the evaluation documentation does not contain clinical or toxicological information | 9 170 |
|  |  (b) if the evaluation documentation contains clinical or toxicological information, and the total number of pages is: |  |
|  |  (i) not over 50 pages | 9 170 |
|  |  (ii) over 50 pages, but not over 250 pages | 11 800 |
|  |  (iii) over 250 pages, but not over 500 pages | 16 100 |
|  |  (iv) over 500 pages, but not over 1 000 pages | 21 400 |
|  |  (v) over 1 000 pages, but not over 2 000 pages | 32 100 |
|  |  (vi) over 2 000 pages, but not over 3 000 pages | 42 800 |
|  |  (vii) over 3 000 pages | 64 100 |
| 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 (b) if the evaluation documentation contains clinical or toxicological information, and the total number of pages is: | 9 170 |
|  |  (i) not over 50 pages | 9 170 |
|  |  (ii) over 50 pages, but not over 250 pages | 11 800 |
|  |  (iii) over 250 pages, but not over 500 pages | 16 100 |
|  |  (iv) over 500 pages, but not over 1 000 pages | 21 400 |
|  |  (v) over 1 000 pages, but not over 2 000 pages | 32 100 |
|  |  (vi) over 2 000 pages, but not over 3 000 pages | 42 800 |
|  |  (vii) over 3 000 pages | 64 100 |
| 8 | Application fee for the purposes of paragraph 37 (1) (g) of the Act | 890 |
| 9 | (a) Fee for paragraphs 38 (1) (c), 41 (1) (f) 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:  | 580 |
|  |  (i) the manufacture of therapeutic goods; or |  |
|  |  (ii) a step 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; or |  |
|  |  (v) the manufacture of diagnostic goods for in vitro use |  |
|  | (b) Fee for paragraphs 38 (1) (c), 41 (1) (f) and 58 (3) (b) of the Act for inspection outside Australia, per hour, per inspector, for inspection of a kind mentioned in paragraph (a) | 1 190 |
| 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 | 580 |
| 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 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 | 790 |
| 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 | 580 |
| 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 | 580 |
| 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 | 1 150 |
|  |  (b) over 10 pages, but not over 50 pages | 9 920 |
|  |  (c) over 50 pages, but not over 100 pages | 22 100 |
|  |  (d) over 100 pages, but not over 1 000 pages | 29 600 |
|  |  (e) over 1 000 pages, but not over 3 000 pages | 46 300 |
|  |  (f) over 3 000 pages, but not over 4 000 pages | 61 500 |
|  |  (g) over 4 000 pages | 74 900 |
| 9B | Evaluation fee for assessing, for paragraph 26 (1) (d) of the Act, whether a therapeutic device is safe for the purposes for which it is to be used | 15 900 |
| 9C | Fee for evaluating documents and other information, relating to the safety of a listed therapeutic device, obtained under paragraph 31 (2) (f) of the Act | 15 900 |
| 9D | Fee for evaluation, under subsection 9D (1), (2) or (3), subsection 24 (1) or paragraph 26 (1) (d) of the Act, of data relating to the device component of a medicine (in addition to the fee prescribed in item 4 or 5 for evaluating the medicine): |  |
|  |  (a) for a device component to which Chapter 3 of the Act applies | The fee applicable under item 5A, 6, 7 or 9B for an evaluation of that nature |
|  |  (b) for a device component to which Chapter 4 of the Act applies | 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 | 140 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 |
| 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, 5, 6 or 7 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, 5, 6 or 7 for an evaluation of that nature |
| 14 | Fee for notification of intention to sponsor a clinical trial using a specified medicine | 310 |
| 14A | Fee for notification of intention to sponsor a clinical trial using a specified therapeutic device, if the sponsor of the device notifies the Secretary, in accordance with item 3 of Schedule 5A, of 1 or more bodies or organisations conducting the trial for the sponsor, including the sponsor, if the sponsor is conducting the trial (whether or not the sponsor has previously notified the Secretary of 1 or more bodies or organisations conducting the trial) | 310 |
| 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 |
| 17 | Fee for an application, under regulation 5F, for approval of an advertisement intended to be published in specified media (other than broadcast media): |  |
|  |  (a) if the time needed to process the application is an hour or less — for an advertisement: |  |
|  |  (i) of not more than 100 words | 210 |
|  |  (ii) of more than 100 words | 260 |
|  |  (iii) of more than 300 words (including an advertorial) | 410 |
|  |  (iv) that is intended for publication in the classified advertisement columns of a newspaper or other publication | 100 |
|  |  (b) if the time needed to process the application is more than an hour | The fee applicable under paragraph (a) plus $180 for each additional hour or part of an hour |
|  |  (c) if the application is for approval of a minor change to an approved advertisement (other than a change to information of the kind mentioned in paragraph 5C (2) (b), (e) or (f) of these Regulations) and the application is made more than 3 months after the advertisement was approved | 100 |
|  |  (d) if the application is for approval of an advertisement that is identical to an approved advertisement the approval number of which has expired under subregulation 5J (3) | 50% of the fee applicable under paragraph (a) and, if applicable, paragraph (b) |
|  |  (e) if the application is for approval of a variation of an approved advertisement the approval number of which has not expired under subregulation 5J (3) | 50% of the fee applicable under paragraph (a) and, if applicable, paragraph (b) |
| 17A | Fee for an application, under regulation 5F, for approval of an advertisement intended to be broadcast in broadcast media: |  |
|  |  (a) if the time needed to process the application is an hour or less — for an advertisement that is: |  |
|  |  (i) a television or cinema advertisement of not more than 150 seconds, including up to 3 variations of the advertising concept for the same product | 1 050 |
|  |  (ii) a television advertisement for a retail outlet that is intended to be broadcast on 1 regional station only in that station’s regional area | 550 |
|  |  (iii) a television advertorial of more than 150 seconds: |  |
|  |  (A) for the first minute of each script | 790 |
|  |  (B) for each additional minute or part of a minute of each script | 220 |
|  |  (iv) a radio advertisement, including up to 6 variations of the advertising concept for the same product | 380 |
|  |  (v) a radio advertisement that is intended to be broadcast in a regional area only, including up to 6 variations of the advertising concept for the same product | 270 |
|  |  (vi) a still cinema media advertisement (including outdoor media): |  |
|  |  (A) of not more than 100 words | 210 |
|  |  (B) of not more than 300 words | 260 |
|  |  (C) of more than 300 words | 410 |
|  |  (b) if the time needed to process the application is more than an hour | The fee applicable under paragraph (a) plus $180 for each additional hour or part of an hour |
|  |  (c) if the application is for approval of a minor change to an approved advertisement (other than a change to information of the kind mentioned in paragraph 5C (2) (b), (e) or (f) of these Regulations) and the application is made more than 3 months after the advertisement was approved | 50% of the fee applicable under paragraph (a) and, if applicable, paragraph (b) |
|  |  (d) if the application is for approval of an advertisement that is identical to an approved advertisement the approval number of which has expired under subregulation 5J (3) | 50% of the fee applicable under paragraph (a) and, if applicable, paragraph (b) |
|  |  (e) if the application is for approval of a variation of an approved advertisement the approval number of which has not expired under subregulation 5J (3) | 50% of the fee applicable under paragraph (a) and, if applicable, paragraph (b) |
| 18 | Fee for testing a sample of, and providing advice in relation to, a prescription medicine on request by the Pharmaceutical Benefits Program of the Department before listing the medicine in the Pharmaceutical Benefits Listing Program of the Department | 1 930 |

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:

 (a) a change requiring submission and evaluation of clinical data;

 (b) extension of an indication;

 (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 (other than a change that is a major variation) to the entry of the biological in the Register for any of the following:

 (a) a change requiring evaluation of quality and manufacturing information;

 (b) a new manufacturing site;

 (c) a change in specification;

 (d) a change in container.

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 | $950 for each application  |
| 2 | Application for inclusion of a Class 2, Class 3 or Class 4 biological in the Register for paragraph 32DD (2) (e) of the Act | $950 for each application |
| 3 | Application for a manufacturing licence for paragraph 37 (1) (g) of the Act | $950 for each application |
| 4 | Evaluation of a Class 2 biological for inclusion in the Register for subsection 32DI (1) of the Act | $63 400 for each evaluation |
| 5 | Evaluation of a Class 3 biological for inclusion in the Register for subsection 32DI (1) of the Act | $126 700 for each evaluation |
| 6 | Evaluation of a Class 4 biological for inclusion in the Register for subsection 32DI (1) of the Act | $205 900 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) | $20 500 for each evaluation |
| 8 | Application for variation to information about a biological included in the Register under subsection 9D (3AA) or (3A) of the Act  | $950 for each application |
| 9 | Evaluation of a product dossier for variation to information of a Class 2 biological included in the Register under subsection 9D (3AA) or (3A) of the Act  | $5 810 for each evaluation |
| 10 | Evaluation of a product dossier for a minor variation to information about a Class 3 or Class 4 biological included in the Register under subsection 9D (3AA) or (3A) of the Act  | $15 300 for each evaluation |
| 11 | Evaluation of a product dossier for a major variation to information about a Class 3 or Class 4 biological included in the Register under subsection 9D (3A) of the Act | $30 100 for each evaluation |
| 12 | Inspection fee — initial manufacturing audit (Australia and overseas) for paragraphs 32DE (1) (e), 38 (1) (c) and 58 (3) (b) of the Act | $18 900 for each inspection |
| 13 | Inspection fee – subsequent Manufacturing Audit (Australia and overseas) for paragraphs 41 (1) (f) and 58 (3) (b) of the Act | $14 300 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 | $580 for each hour of preparation by each inspector |
| 15 | 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 | Amount of costs and reasonable expenses of travel by each inspector, including costs for accommodation and allowance outside Australia |
| 16 | Evaluation fee for subsection 32CK (4) of the Act | $22 800 for each evaluation |
| 17 | Notification fee for a biological mentioned in item 3 of Schedule 5A | $300 for each evaluation |

Schedule 10 Therapeutic goods for evaluation

(subregulations 16C (1), 16D (1), 16F (1) and 16G (1))

Part 1 Evaluation by Office of Medicines Authorisation of prescription and other medicines

| Column 1Item | Column 2Product |
| --- | --- |
| 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, unless coated on a therapeutic device |
| 14 | therapeutic goods referred to the Office of Medicines Authorisation 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 by the Office of Complementary Medicines

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 1Item | Column 2Product |
| 1 | a complementary medicine |
| 2 | an excipient in complementary medicine |
| 3 | therapeutic goods referred for evaluation to the Office of Complementary Medicines of the Therapeutic Goods Administration within the Department |

Part 3 Evaluation by Office of Medicines Authorisation of non-prescription and other medicines

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 1Item | Column 2Product |
| --- | --- |
| 1 | an antiseptic |
| 2 | a sunscreen preparation |
| 3 | all other therapeutic goods, except a therapeutic device, not mentioned in another Part of this Schedule |
| 4 | an excipient in therapeutic goods mentioned in this Part |
| 5 | therapeutic goods referred to the Office of Medicines Authorisation of the Therapeutic Goods Administration within the Department for the purpose of evaluation as a non-prescription medicine |

Schedule 12 Patient information documents

(subregulation 9A (1))

A patient information document about a medicinal product must be:

* written in English
* clearly legible
* written in language that will easily be understood by patients
* consistent with product information about the product.

A patient information document must include the following:

1. Identification

The name of the medicinal product, which is the name given to the product by the sponsor, including or followed by the non‑proprietary name(s) of the active ingredient(s) and the dosage form or strength, or both, of the product.

A statement of the active ingredients expressed quantitatively and excipients expressed qualitatively, using their common names, in the case of each presentation of the product.

The pharmaceutical form and the contents by weight, volume or number of doses of the product, in the case of each presentation of the product, together with its identifying Australian Register number.

2. What the product is used for and how it works

The therapeutic indications, unless a competent authority determines that dissemination of such information may have serious disadvantages for the patient.

The pharmaco‑therapeutic group, or type of activity, if there is a term that is easily comprehensible for the patient. If not, a simple description of what the medicinal product is for and how it works, in 1 or 2 sentences.

3. Advice before using the medicinal product

A list of factors that are useful to consider before taking the medicinal product, including, if appropriate:

* contraindications, including consideration of whether the patient has experienced previous allergic reactions
* precautions for use, taking into account the particular condition of certain categories of users, such as the elderly, children, infants, pregnant or breastfeeding women, persons with specific pathological conditions
* potential effects of the medicinal product on the ability to drive vehicles or to operate machinery
* interactions with other medicinal products or other forms of interaction (for example with alcohol, tobacco, foodstuffs) which may affect the action of the product
* special warnings, such as effects on sensitivity to sun exposure.

4. How to use the medicinal product properly

The necessary and usual instructions for proper use of the medicinal product, in particular:

* the dosage, together with an indication that this may not always apply and may be modified by the prescriber
* the method and, if necessary, route of administration
* the frequency of administration, specifying, if necessary, the appropriate time at which the medicinal product should or must be used

In addition, depending upon the nature of the therapeutic goods:

* the duration of treatment, if it should be limited
* the expected effect of using the medicinal product
* what to do if 1 or more doses have not been taken
* the way the treatment should be stopped, if stopping the treatment may lead to withdrawal or other adverse effects.

5. Further information

For example, habit forming potential, whether a doctor’s prescription is required.

6. Unwanted effects

A description of the undesirable effects that can occur under normal use of the medicinal product and, if necessary, the action to be taken if experienced.

The patient should be expressly invited to communicate any undesirable effect, especially if it is not mentioned in the patient information document, to his or her doctor or pharmacist.

7. In case of overdose

The action to be undertaken in the case of overdose (for example, symptoms and emergency procedures).

8. Storage conditions

An indication of the appropriate storage conditions; a reference to the expiry date indicated on the label, with a warning against using the medicinal product after this date; if appropriate, a warning against visible signs of deterioration.

9. Where to go for further information

A direction to patients to discuss any aspect with the doctor or pharmacist and, if appropriate, where further information may be obtained.

10. Sponsor

The name and address of the Australian sponsor of the medicinal product.

11. Date of information

The date on which the patient information document was last revised.

*Note 1*   ***Common name*** is the name approved under the Australian Approved Names List. For ***Australian Approved Names List***, see regulation 2.

*Note 2*   The information need not appear in the order outlined above. For example, the subsidiary information under “*Identification*” could appear at the end of the patient information document.

Schedule 13 Patient information documents

(subregulation 9A (1A))

A patient information document about a medicinal product must be:

* written in English
* clearly legible
* written in language that will easily be understood by patients
* consistent with product information about the product.

A patient information document must include the following:

1. Identification

The name of the medicinal product, which is the name given to the product by the sponsor.

A statement of the active ingredients expressed quantitatively and excipients expressed qualitatively, using their common names, in the case of each presentation of the product.

The pharmaceutical form and the contents by weight, volume or number of doses of the product, in the case of each presentation of the product, together with its identifying Australian Register number.

2. What the product is used for and how it works

The therapeutic indications, unless a competent authority determines that dissemination of such information may have serious disadvantages for the patient.

The pharmaco‑therapeutic group, or type of activity, if there is a term that is easily comprehensible for the patient. If not, a simple description of what the medicinal product is for and how it works, in 1 or 2 sentences.

3. Advice before using the medicinal product

A list of factors that are useful to consider before taking the medicinal product, including, if appropriate:

• contraindications, including consideration of whether the patient has experienced previous allergic reactions

• precautions for use, taking into account the particular condition of certain categories of users, such as the elderly, children, infants, pregnant or breastfeeding women, persons with specific pathological conditions

• potential effects of the medicinal product on the ability to drive vehicles or to operate machinery

• interactions with other medicinal products or other forms of interaction (for example with alcohol, tobacco, foodstuffs) which may affect the action of the product

• special warnings, such as effects on sensitivity to sun exposure.

4. How to use the medicinal product properly

The necessary and usual instructions for proper use of the medicinal product, in particular:

• the dosage, together with an indication that this may not always apply and may be modified by the prescriber

• the method and, if necessary, route of administration

• the frequency of administration, specifying, if necessary, the appropriate time at which the medicinal product should or must be used

In addition, depending upon the nature of the therapeutic goods:

• the duration of treatment, if it should be limited

• the expected effect of using the medicinal product

• what to do if 1 or more doses have not been taken

• the way the treatment should be stopped, if stopping the treatment may lead to withdrawal or other adverse effects.

5. Further information

For example, habit forming potential.

6. Unwanted effects

A description of the undesirable effects that can occur under normal use of the medicinal product and, if necessary, the action to be taken if experienced.

The patient should be expressly invited to communicate any undesirable effect, especially if it is not mentioned in the patient information document, to his or her health care practitioner or pharmacist.

7. In case of overdose

The action to be undertaken in the case of overdose (for example, symptoms and emergency procedures).

8. Storage conditions

An indication of the appropriate storage conditions; a reference to the expiry date indicated on the label, with a warning against using the medicinal product after this date; if appropriate, a warning against visible signs of deterioration.

9. Where to go for further information

A direction to patients to discuss any aspect with the health care practitioner or pharmacist and, if appropriate, where further information may be obtained.

10. Sponsor

The name and address of the Australian sponsor of the medicinal product.

11. Date of information

The date on which the patient information document was last revised.

*Note 1*   ***Common name*** is the name approved under the Australian Approved Names List. For ***Australian Approved Names List***, see regulation 2.

*Note 2* The information need not appear in the order outlined above. For example, the subsidiary information under “*Identification*” could appear at the end of the patient information document.

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 homeopathic 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 15 Infringement notices

(regulation 45B)

1 Definitions

 In this Schedule:

***issuing officer*** means the Secretary, or an officer to whom the Secretary has given a delegation under subregulation 47 (1A).

2 Issue of infringement notice

 (1) If there are reasonable grounds for believing that a person has committed an offence of strict liability against the Act, or has contravened a civil penalty provision, an issuing officer may serve an infringement notice, or cause an infringement notice to be served, on the person in accordance with clause 4.

 (2) An infringement notice for an alleged offence or an alleged contravention must be served on a person within 12 months after the day the offence or contravention is alleged to have been committed.

 (3) If an infringement notice given to a person for an alleged offence or an alleged contravention is withdrawn, an issuing officer may give the person a new infringement notice for the alleged offence or the alleged contravention.

 (4) An infringement notice may be withdrawn by the issuing officer at any time before the person to whom the notice has been issued pays in full the amount of the penalty stated in the notice.

 (5) An issuing officer who withdraws an infringement notice under subclause (4) must give written notice to the person against whom the notice was issued within 7 days after the withdrawal of the notice.

3 Contents of infringement notice

 (1) An infringement notice must set out the following information:

 (a) a unique identification code;

 (b) the name of the issuing officer;

 (c) its date of issue;

 (d) the full name, or the surname and initials, and the address of the person to whom it is issued;

 (e) brief details of the alleged offence or the alleged contravention, including:

 (i) the date, and (if known) the time, when it is alleged to have been committed; and

 (ii) the place where it is alleged to have been committed; and

 (iii) the provision of the Act alleged to have been contravened;

 (f) the penalty for the alleged offence or the alleged contravention payable under the notice;

 (g) the maximum penalty that a court could impose for the alleged offence or the alleged contravention;

 (h) a statement that if the person prefers not to have the matter dealt with by a court, the person may signify that preference by paying the penalty specified in the infringement notice:

 (i) within 28 days after the service of the notice; or

 (ii) if a further period is allowed, before the end of that period; or

 (iii) if payment by instalments is permitted, in accordance with that permission;

 (i) how, and where, the penalty can be paid;

 (j) a statement that, if an infringement notice is not withdrawn and the person to whom it is issued pays in full the penalty stated in the notice in accordance with this Schedule:

 (i) any liability of the person for the alleged offence or the alleged contravention is discharged; and

 (ii) the person will not be prosecuted in a court for the alleged offence, or proceedings will not be brought against the person for the alleged contravention; and

 (iii) the person will not be taken to have admitted liability for the alleged offence or the alleged contravention; and

 (iv) the person will not be taken to have been convicted of the offence or to be liable for the contravention;

 (k) how the person can apply:

 (i) for an extension of time to pay the penalty stated in the notice; or

 (ii) to pay the penalty by instalments; or

 (iii) to have the notice withdrawn;

 (l) the telephone number or the address of an officer in the office of the Therapeutic Goods Administration to whom inquiries can be made about the notice;

 (m) the signature of the issuing officer.

 (2) An infringement notice may contain any other information that the issuing officer considers necessary.

4 Service of infringement notices

 (1) An infringement notice must be served on the person to whom it is issued.

 (2) An infringement notice may be served on an individual:

 (a) by giving it to the individual; or

 (b) by leaving it at, or by sending it by post or electronically to the address, including the electronic address, of the place of residence or business of the individual last known to the issuing officer, or the address given to the Secretary by the individual’s authorised agent; or

 (c) by giving it to someone at that place who:

 (i) lives or is employed, or apparently lives or is employed, there; and

 (ii) is apparently over 16 years of age.

 (3) An infringement notice may be served on a body corporate:

 (a) by leaving it at, or by sending it by post or electronically to the address, including the electronic address, of the head office, a registered office, a principal office or the address given to the Secretary by an officer of the body corporate or its authorised agent; or

 (b) by giving it to someone who is, or who the issuing officer has reason to believe is, a director of the body corporate residing in Australia.

 (4) For paragraphs (2) (b) and (3) (a):

***authorised agent*** means a person, including a body corporate, nominated in writing to the Therapeutic Goods Administration by an individual or body corporate to act on behalf of the individual or body corporate in relation to therapeutic goods.

5 Extension of time to pay penalty

 (1) Within 28 days after being served with an infringement notice, a person may apply in writing to the issuing officer for a further period of up to 28 days after the initial 28 days in which to pay the penalty stated in the notice.

 (2) A person cannot apply under subclause  (1) if the person has applied under clause 7 for withdrawal of the notice.

 (3) The application must:

 (a) include the notice’s unique specification code; and

 (b) set out the reasons for the application.

 (4) Within 14 days after receiving the application, the issuing officer must:

 (a) grant, or refuse to grant, the application; and

 (b) notify the person in writing of the decision and, if the decision is a refusal, the reasons for the decision.

 (5) If the issuing officer has not granted or refused to grant the application within the period mentioned in subclause (4), the application is to be taken to have been granted.

 (6) The person must pay the penalty:

 (a) if the application is approved — in accordance with the decision; or

 (b) if the application is refused — within the later of:

 (i) the end of the initial 28 days; and

 (ii) 7 days after receiving the notice of the refusal; or

 (c) if subclause (5) applies — within a further 28 days after the end of the initial 28 days mentioned in subclause (1).

6 Payment of penalty by instalments

 (1) Within 28 days after being served with an infringement notice, a person may apply, in writing, to the issuing officer to pay the penalty stated in the notice by instalments, over a period of up to 6 months.

 (2) A person cannot apply under subclause (1) if the person has applied under clause 7 for withdrawal of the notice.

 (3) The applicant must:

 (a) include the notice’s unique identification code; and

 (b) set out the reasons for the application; and

 (c) state the amount and frequency of the instalments that the person proposes to pay.

 (4) Within 14 days after receiving the application, the issuing officer must:

 (a) grant or refuse to grant the application; and

 (b) give the person written notice of the decision, including:

 (i) if the application is granted — the amount and frequency of the instalments; or

 (ii) if the application is refused — the reasons for the decision.

 (5) If the issuing officer has not granted or refused to grant the application within the period mentioned in subclause (4), the application is to be taken to have been granted.

 (6) The person must pay the penalty:

 (a) if the application is granted — in the manner outlined in the decision; or

 (b) if the application is refused — within the later of:

 (i) 28 days; and

 (ii) 7 days after receiving the notice of the decision; or

 (c) if subclause (5) applies:

 (i) within the 6 months mentioned in subclause (1); and

 (ii) unless otherwise agreed in writing by the issuing officer — in equal monthly instalments.

7 Withdrawal of infringement notice

 (1) Within 28 days after being served with an infringement notice, a person who considers the notice to be defective may apply in writing to the issuing officer for the withdrawal of the infringement notice.

 (2) The application must include:

 (a) the notice’s unique identification code; and

 (b) any facts or matters that the person believes should be taken into account about the alleged offence or contravention.

 (3) Within 14 days after receiving the application, the issuing officer must:

 (a) having regard to the information mentioned in subclause (2), withdraw or refuse to withdraw the notice; and

 (b) notify the person, in writing, of the decision and, if the decision is a refusal, the reasons for the decision.

 (4) If the issuing officer does not withdraw or refuse to withdraw the notice before the end of the period mentioned in subclause (3), the application is taken to have been granted.

 (5) If the issuing officer decides to refuse the application, notice of the decision must state:

 (a) that if the infringement notice penalty is paid by the person within 28 days after receiving notice of the decision, the person will not be prosecuted for the alleged offence or proceedings will not be instituted for the alleged contravention; and

 (b) that if the penalty is not paid in accordance with paragraph (a), the person may be prosecuted for the alleged offence or proceedings instituted for the alleged contravention.

 (6) If the issuing officer refuses to withdraw an infringement notice, and if the person elects to pay the penalty stated in the notice, the person must pay the penalty within 28 days after receiving the notice of the refusal.

8 Notice of withdrawal of infringement notice

 A notice withdrawing an infringement notice served on a person must:

 (a) include the following information:

 (i) the person’s full name, or surname and initials, and address;

 (ii) the date of issue of the infringement notice; and

 (b) state that the notice is withdrawn.

9 Effect of payment of infringement notice penalty

 (1) If a person served with an infringement notice that is not withdrawn pays the infringement notice penalty in full in accordance with this Schedule:

 (a) the person’s liability for the alleged offence or the alleged contravention is discharged; and

 (b) further proceedings cannot be taken against the person for the alleged offence or the alleged contravention; and

 (c) the person is not convicted of the alleged offence or found liable for the alleged contravention.

 (2) Subclause (1) applies to a person who makes an arrangement to pay the infringement notice penalty by instalments, only if the person makes payments in accordance with the arrangement.

10 Refund of penalty

 If an infringement notice is withdrawn after any amount of the penalty stated in the notice has been paid, including when the penalty has not been fully paid or has been fully paid but not within the approved period, the Commonwealth must refund the amount of the penalty paid to the person who paid it.

11 Matter not to be taken into account in determining sentence

 (1) This clause applies if a person served with an infringement notice:

 (a) elects not to pay the penalty stated in the infringement notice; and

 (b) is found by a court to have committed the offence or contravened the civil penalty provision mentioned in the infringement notice.

 (2) In determining the penalty to be imposed, the court must not take into account the fact that the person chose not to pay the penalty stated in the infringement notice.

12 Infringement notice not compulsory

 Nothing in this Schedule is to be taken:

 (a) to require an issuing officer to serve an infringement notice, or to cause an infringement notice to be served, on a person suspected of having committed an offence of strict liability or of having contravened a civil penalty provision under the Act; or

 (b) to affect the liability of a person to be prosecuted for an alleged offence or an alleged contravention of a civil penalty provision, if:

 (i) an infringement notice is not served on the person for the offence or contravention; or

 (ii) an infringement notice is served, and withdrawn; or

 (c) to limit the penalty that may be imposed by a court on a person convicted of an offence or found liable for the contravention of a civil penalty provision.

Schedule 16 Classes of biologicals

*Note*This Schedule is reserved for future use.

Notes to the *Therapeutic Goods Regulations 1990*

Note 1

The *Therapeutic Goods Regulations 1990* (in force under the *Therapeutic Goods Act 1989*) as shown in this compilation comprise Statutory Rules No.  amended as indicated in the Tables below.

For all relevant information pertaining to application, saving or transitional provisions *see* Table A.

Table of Instruments

| Year and number | Date of notification in *Gazette* or FRLI registration | Date ofcommencement | Application, saving ortransitional 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 1991Remainder: 30 Apr 1991 | — |
| 1991 No. 485 | 24 Dec 1991 | 24 Dec 1991 | — |
| 1992 No. 19 | 31 Jan 1992 | R. 10: 1 July 1992Remainder: 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 1993Remainder: 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 1995Rr. 8, 9.2, 10.6 and 11.7: 1 Jan 1996R. 10.7: 1 Oct 1996Rr. 13.2 and 14.4: 1 Jan 1997Remainder: 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 *(a)* | 5 Feb 1996 | 5 Feb 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 | — |
| 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 1997Remainder: 1 Jan 1998 | — |
| 1997 No. 400 | 24 Dec 1997 | 24 Dec 1997 | — |
| 1997 No. 401 *(b)* | 24 Dec 1997 | 24 Dec 1997 | — |
| 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 2000Remainder: 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 2001Remainder: 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 2002Remainder: 1 Jan 2003 | — |
| 2002 No. 345 | 20 Dec 2002 | Rr. 1–3 and Schedule 1: 20 Dec 2002Remainder: 1 Jan 2003 | — |
| 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 2003Remainder: 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 (*see* F2005L02312) | 20 Aug 2005  | — |
| 2006 No. 122 | 2 June 2006 (*see* F2006L01615) | 3 June 2006 | — |
| 2006 No. 212 | 10 Aug 2006 (*see* F2006L02573) | 11 Aug 2006 | — |
| 2007 No. 161 | 25 June 2007 (*see* F2007L01521) | 1 July 2007 | — |
| 2008 No. 117 | 20 June 2008 (*see* F2008L01367) | 1 July 2008 | — |
| 2009 No. 63 | 15 Apr 2009 (*see* F200900839) | 16 Apr 2009 | — |
| 2009 No. 140 | 25 June 2009 (*see* F2009L01826) | 26 June 2009 | — |
| 2009 No. 141 | 25 June 2009 (*see* F2009L02019) | 1 July 2009 | — |
| 2009 No. 179 | 9 July 2009 (*see* F2009L02089) | 10 July 2009 | — |
| 2009 No. 228 | 10 Sept 2009 (*see* F2009L02935) | 11 Sept 2009 | — |
| 2009 No. 374 | 16 Dec 2009 (*see* F2009L04018) | Rr. 1–4 and Schedule 1:1 Jan 2010Schedule 2: 25 Jan 2010 | R. 4 |
| 2010 No. 26 | 3 Mar 2010 (*see* F2010L00470) | 1 July 2010 | Rr. 4–7 |
| 2010 No. 129 | 21 June 2010 (*see* F2010L01285) | 1 July 2010 | — |
| 2010 No. 130 | 21 June 2010 (*see* F2010L01282) | 1 July 2010 | — |
| 2010 No. 266 | 28 Oct 2010 (*see* F2010L02771) | 29 Oct 2010 | R. 4 |
| 2011 No. 30 | 16 Mar 2011 (*see* F2011L00434) | 31 May 2011 (*see* r. 2) | — |
| 2011 No. 102 | 21 June 2011 (*see* F2011L01100) | 1 July 2011 | — |
| 2011 No. 281 | 8 Dec 2011 (*see* F2011L02595) | Rr. 1–3 and Schedule 1:9 Dec 2011Schedule 2: 1 Mar 2012 | — |
| 2012 No. 142 | 29 June 2012 (*see* F2012L01448) | 30 June 2012 | — |
| 2012 No. 143 | 29 June 2012 (*see* F2012L01455) | 1 July 2012 | — |
| 2012 No. 251 | 9 Nov 2012 (*see* F2012L02161) | 10 Nov 2012 | — |

*(a)* Statutory Rules 1996 No. 25 was disallowed by the House of Representatives on 10 September 1996.

*(b)* Statutory Rules 1997 No. 401 was disallowed by the Senate on 31 March 1998.

Table of Amendments

| ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted |
| --- |
| Provision affected | How affected |
| **Part 1** |  |
| R. 1  | rs. 1998 No. 369 |
| R. 2  | am. 1991 No. 485; 1992 No. 332; 1994 No. 364; 1995 Nos. 111, 208 and 328; 1997 Nos. 398, 399 and 400; 1998 No. 369; 1999 Nos. 62 and 324; 2000 Nos. 29, 48 and 358; 2001 No. 159; 2002 No. 234; 2003 Nos. 111, 151, 301 and 361; 2004 No. 127; 2009 No. 374; 2010 No. 26; 2011 Nos. 30 and 102; 2012 No. 251 |
| Note to r. 2  | ad. 1999 No. 62 |
|  | am. 2011 No. 102; 2012 No. 251 |
| R. 2A  | ad. 2003 No. 361 |
| R. 3  | am. 1992 Nos. 89 and 430 |
|  | rs. 1995 No. 111 |
|  | am. 1996 No. 200 |
|  | rs. 2003 No. 361 |
|  | am. 2010 No. 26; 2011 Nos. 102 and 281 |
| R. 3AA  | ad. 2011 No. 102 |
| R. 3A  | ad. 2003 No. 301 |
|  | am. 2005 No. 192 |
| **Part 2** |  |
| **Division 1** |  |
| Heading to Div. 1 of Part 2  | ad. 1997 No. 400 |
| Div. 1 of Part 2  | rs. 2003 No. 301 |
| R. 4  | am. 1992 No. 19; 2001 No. 159 |
|  | rs. 2003 No. 301 |
| R. 4A  | ad. 2003 No. 301 |
| R. 5  | rep. 2003 No. 301 |
| R. 5A  | ad. 1992 No. 19 |
|  | rep. 2003 No. 301 |
| **Division 2** |  |
| Div. 2 of Part 2  | ad. 1997 No. 400 |
| R. 5B  | ad. 1997 No. 400 |
|  | am. 1998 Nos. 227 and 369; 1999 No. 62; 2000 No. 48; 2001 No. 159; 2002 No. 234; 2003 No. 301 |
| R. 5BA  | ad. 2003 No. 301 |
| R. 5C  | ad. 1997 No. 400 |
|  | am. 2001 No. 159 |
| Rr. 5D, 5E  | ad. 1997 No. 400 |
|  | rep. 1999 No. 62 |
| R. 5F  | ad. 1997 No. 400 |
|  | am. 1999 No. 324 |
| R. 5G  | ad. 1997 No. 400 |
|  | am. 1999 No. 324; 2000 No. 48; 2003 No. 301 |
| R. 5H  | ad. 1997 No. 400 |
| R. 5J  | ad. 1997 No. 400 |
|  | am. 2000 No. 48 |
| R. 5K  | ad. 1997 No. 400 |
| R. 5L  | ad. 1997 No. 400 |
|  | am. 1999 No. 62; 2000 No. 48 |
| R. 5M  | ad. 1997 No. 400 |
| R. 5N  | ad. 1997 No. 400 |
| R. 5P  | ad. 1997 No. 400 |
| R. 5Q  | ad. 1997 No. 400 |
|  | am. 1998 No. 369; 2000 No. 48; 2001 No. 159; 2003 No. 301; 2011 No. 281 |
| **Division 3** |  |
| Heading to Div. 3 of Part 2  | ad. 1997 No. 400 |
|  | rs. 2003 No. 301 |
| Div. 3 of Part 2  | 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 |
| Note to r. 6 (2)  | ad. 2002 No. 9 |
|  | rep. 2003 No. 301 |
| Note to r. 6 (5)  | ad. 2002 No. 9 |
|  | rep. 2003 No. 301 |
| Rr. 6AA, 6AB  | ad. 2000 No. 48 |
|  | rep. 2003 No. 301 |
| R. 6AA  | ad. 2009 No. 374 |
| R. 6A  | ad. 1995 No. 208 |
|  | rs. 2003 No. 301; 2005 No. 192 |
| R. 6B  | ad. 2003 No. 301 |
| R. 7  | rs. 2003 No. 301 |
| Rr. 7A–7H  | ad. 2000 No. 48 |
|  | rep. 2003 No. 301 |
| R. 7J  | ad. 2000 No. 48 |
|  | rep. 2003 No. 301 |
| **Division 4** |  |
| Heading to Div. 4 of Part 2  | ad. 1997 No. 400 |
|  | rs. 2003 No. 301 |
| Div. 4 of Part 2  | rs. 2003 No. 301 |
| R. 8  | am. 1997 No. 400 |
|  | rs. 2003 No. 301 |
|  | am. 2006 No. 122 |
| R. 8A  | ad. 2003 No. 301 |
|  | am. 2006 No. 122 |
| **Division 5** |  |
| Div. 5 of Part 2  | ad. 1997 No. 400 |
|  | rep. 2000 No. 48 |
|  | ad. 2003 No. 301 |
| R. 9  | rs. 2000 No. 48; 2003 No. 301 |
| 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 |
| Note to r. 9A (1)  | ad. 2003 No. 257 |
| R. 9B  | ad. 2003 No. 257 |
|  | am. 2011 No. 102 |
| 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 |
|  | 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. 2002 No. 234 |
| R. 10A (formerly r. 13) | 2002 No. 234 |
| R. 10B (formerly r. 14) | 2002 No. 234rs. 2011 No. 30 |
| R. 10C (formerly r. 14A) | 2002 No. 234 |
| 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 |
| **Division 2C.3** |  |
| Div. 2C.3 of Part 2C  | ad. 2011 No. 30 |
| R. 10G  | ad. 2011 No. 30 |
| R. 10H  | ad. 2011 No. 30 |
|  | am. 2011 No. 281 |
| R. 10I  | ad. 2011 No. 30 |
| R. 10J  | ad. 2011 No. 30 |
| **Part 3** |  |
| Heading to Part 3  | rs. 2011 No. 30 |
| R. 10A  | ad. 2001 No. 252 |
| Renumbered r. 11  | 2002 No. 234 |
|  | am. 2004 No. 127 |
| 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 |
| 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 |
| Heading to r. 12A  | am. 1999 No. 62 |
|  | rs. 2011 No. 30 |
| R. 12A  | ad. 1991 No. 485 |
|  | am. 1999 No. 62; 2000 No. 358; 2002 Nos. 9 and 234; 2011 No. 30 |
| R. 12AAA  | ad. 2003 No. 111 |
|  | rep. 2010 No. 266 |
| Heading to r. 12AAB  | rs. 2011 No. 30 |
| R. 12AAB  | ad. 2003 No. 111 |
|  | am. 2011 No. 30 |
| R. 12AA  | ad. 2000 No. 358 |
|  | am. 2011 No. 30 |
| R. 12AB  | ad. 2000 No. 358 |
|  | am. 2003 Nos. 258 and 361; 2011 No. 30 |
| Heading to r. 12AC  | rs. 2003 No. 361 |
| R. 12AC  | ad. 2000 No. 358 |
|  | am. 2003 No. 361 |
| R. 12AD  | ad. 2000 No. 358 |
|  | am. 2002 No. 234; 2011 No. 30 |
| Heading to r. 12B  | rs. 2011 No. 30 |
| R. 12B  | ad. 1991 No. 485 |
|  | am. 1992 No. 19; 1999 No. 62; 2000 No. 358; 2003 Nos. 258 and 361 |
| R. 12C  | ad. 2002 No. 234 |
|  | rep. 2010 No. 26 |
|  | ad. 2011 No. 30 |
| R. 13  | am. 1992 No. 19; 2002 No. 9 |
| Renumbered r. 10A  | 2002 No. 234 |
| R. 14  | am. 2002 No. 9; 2002 No. 234 |
| Renumbered r. 10B  | 2002 No. 234 |
| R. 14A  | ad. 1992 No. 430 |
| Renumbered r. 10C  | 2002 No. 234 |
| Rr. 14B, 14C  | ad. 1992 No. 430 |
|  | rep. 2002 No. 234 |
| R. 15  | am. 1992 No. 19; 1997 No. 398; 1999 No. 62; 2011 No. 102 |
| R. 15A  | ad. 2003 No. 258 |
|  | am. 2010 No. 26; 2011 No. 102 |
|  | rs. 2012 No. 251 |
| R. 16  | am. 1992 No. 89 |
|  | am. 2010 No. 26 |
| R. 16AA  | ad. 2003 No. 151 |
| R. 16AB  | ad. 2011 No. 30 |
| **Part 3A** |  |
| Heading to Part 3A  | am. 1999 No. 62 |
|  | rs. 2000 No. 29 |
| Part 3A  | ad. 1992 No. 19 |
| **Division 1** |  |
| Heading to Div. 1 of Part 3A | ad. 2000 No. 29 |
| R. 16A  | ad. 1992 No. 19 |
|  | am. 2011 No. 281 |
| R. 16B  | ad. 1992 No. 19 |
| R. 16C  | ad. 1992 No. 19 |
|  | am. 1992 No. 109; 1998 No. 227; 1999 No. 62 |
| R. 16D  | ad. 1992 No. 19 |
|  | am. 1992 No. 109; 1998 No. 227; 1999 No. 62; 2003 No. 151 |
| R. 16E  | ad. 1992 No. 19 |
| Heading to r. 16F  | rs. 2003 No. 151 |
| R. 16F  | ad. 1992 No. 19 |
|  | am. 1998 No. 227; 1999 No. 62 |
| R. 16G  | ad. 1992 No. 109 |
|  | am. 1998 No. 227; 1999 No. 62 |
| **Division 2** |  |
| Div. 2 of Part 3A  | ad. 2000 No. 29 |
| Heading to r. 16GA  | rs. 2003 No. 151 |
| R. 16GA  | ad. 2000 No. 29 |
|  | am. 2003 No. 151 |
| **Division 3** |  |
| Div. 3 of Part 3A  | ad. 2011 No. 30 |
| R. 16GB  | ad. 2011 No. 30 |
|  | am. 2011 No. 281 |
| R. 16GC  | ad. 2011 No. 30 |
|  | am. 2011 No. 281 |
| R. 16GD  | ad. 2011 No. 30 |
|  | am. 2011 No. 281 |
| R. 16GE  | ad. 2011 No. 30 |
| R. 16GF  | ad. 2011 No. 30 |
| **Part 3B** |  |
| Part 3B  | ad. 1997 No. 399 |
| R. 16H  | ad. 1997 No. 399 |
|  | am. 1999 No. 62 |
| R. 16I  | ad. 1997 No. 399 |
|  | am. 1999 No. 62 |
| R. 16J  | ad. 1997 No. 399 |
|  | am. 1999 No. 62 |
| **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. 1994 No. 150; 2001 No. 252; 2002 No. 234; 2003No. 361 |
| R. 24  | am. 1991 No. 84; 2002 No. 234; 2004 No. 78 |
| R. 25  | am. 1994 No. 150; 2001 No. 252; 2002 No. 234 |
| R. 26  | am. 1994 No. 150; 2001 No. 252 |
| R. 26A  | ad. 2001 No. 252 |
|  | am. 2002 No. 234 |
| R. 27  | rs. 1994 No. 150 |
|  | am. 2002 No. 234 |
| R. 28  | am. 2002 No. 234 |
| R. 29  | am. 1994 Nos. 150 and 364; 2001 No. 252; 2002 No. 234 |
| R. 30  | am. 2002 No. 234; 2003 No. 361 |
| R. 31  | am. 2001 No. 252; 2002 No. 234 |
| R. 32  | am. 1994 No. 150; 2002 No. 9 |
| R. 33  | am. 2002 No. 9 |
| **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** |  |
| Heading to Div. 1 of Part 6  | ad. 1997 No. 400 |
|  | rs. 2002 No. 234; 2009 No. 374 |
| Div. 1 of Part 6  | rs. 2009 No. 374 |
| R. 34  | am. 1995 No. 208; 1999 No. 62; 2002 No. 234 |
|  | rs. 2009 No. 374 |
| R. 34A  | ad. 2009 No. 374 |
|  | am. 2011 No. 30; 2012 No. 251 |
| R. 34B  | ad. 2009 No. 374 |
| **Division 1A** |  |
| Div. 1A of Part 6  | ad. 2009 No. 374 |
| R. 35  | am. 1991 No. 485; 1999 No. 62 |
|  | rs. 2002 No. 234; 2009 No. 374 |
| R. 35A  | ad. 2009 No. 374 |
|  | am. 20121 No. 251 |
| R. 35B  | ad. 2009 No. 374 |
|  | am. 2011 No. 102 |
| **Division 1B** |  |
| Div. 1B of Part 6  | ad. 2009 No. 374 |
| R. 36  | am. 1991 No. 485; 1999 No. 62; 2002 No. 234 |
|  | rs. 2009 No. 374 |
| R. 36A  | ad. 2009 No. 374 |
|  | am. 2012 No. 251 |
| R. 36B  | ad. 2009 No. 374 |
|  | am. 2011 No. 102 |
| **Division 1C** |  |
| Div. 1C of Part 6  | ad. 2009 No. 374 |
| R. 37  | am. 1997 No. 400 |
|  | rs. 2009 No. 374 |
| R. 37A  | ad. 2009 No. 374 |
|  | am. 2012 No. 251 |
| R. 37B  | ad. 2009 No. 374 |
|  | am. 2011 No. 102 |
| **Division 1D** |  |
| Div. 1D of Part 6  | 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 |
| R. 38B  | ad. 2009 No. 374 |
|  | am. 2011 Nos. 102 and 281 |
| **Division 1DA** |  |
| Div. 1DA of Part 6  | ad. 2011 No. 281 |
| R. 38C  | ad. 2011 No. 281 |
| R. 38D  | ad. 2011 No. 281 |
|  | am. 2012 No. 251 |
| R. 38E  | ad. 2011 No. 281 |
| R. 39  | am. 1997 No. 400 |
|  | rep. 2009 No. 374 |
| **Division 1E** |  |
| Div. 1E of Part 6  | ad. 2009 No. 374 |
| R. 39  | ad. 2009 No. 374 |
| R. 39A  | ad. 2009 No. 374 |
|  | am. 2012 No. 251 |
| R. 39B  | ad. 2009 No. 374 |
|  | am. 2011 No. 102 |
| **Division 1EA** |  |
| Div. 1EA of Part 6  | ad. 2011 No. 30 |
| R. 39C  | ad. 2011 No. 30 |
| R. 39D  | ad. 2011 No. 30 |
|  | am. 2012 No. 251 |
| R. 39E  | ad. 2011 No. 30 |
| **Division 1EB** |  |
| Div. 1EB of Part 6  | ad. 2012 No. 251 |
| R. 39F  | ad. 2012 No. 251 |
| R. 39G  | ad. 2012 No. 251 |
| R. 39H  | ad. 2012 No. 251 |
| **Division 1F** |  |
| Div. 1F of Part 6  | 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 |
| 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 |
| **Division 2** |  |
| Div. 2 of Part 6  | ad. 1997 No. 400 |
| R. 42A  | ad. 1997 No. 400 |
| R. 42B  | ad. 1997 No. 400 |
|  | am. 2001 No. 159; 2003 No. 301 |
| R. 42C  | ad. 1997 No. 400 |
|  | am. 1998 No. 369; 2002 No. 234; 2003 Nos. 111 and 258; 2006 No. 122; 2011 No. 102 |
| R. 42D  | ad. 1997 No. 400 |
|  | am. 2003 No. 361 |
| R. 42E  | ad. 1997 No. 400 |
|  | am. 1998 No. 369; 2002 No. 234; 2003 No. 111 |
| R. 42F  | ad. 1997 No. 400 |
| R. 42G  | ad. 1997 No. 400 |
| R. 42H  | ad. 1997 No. 400 |
|  | am. 2000 No. 48 |
| R. 42J  | ad. 1997 No. 400 |
|  | am. 2000 No. 48; 2001 No. 159; 2002 No. 315; 2003 Nos. 258 and 361; 2006 No. 122; 2009 No. 63 |
| R. 42K  | ad. 1997 No. 400 |
|  | am. 1998 No. 369; 2002 No. 234; 2003 No. 111 |
| R. 42L  | ad. 1997 No. 400 |
| R. 42M  | ad. 1997 No. 400 |
| R. 42N  | ad. 1997 No. 400 |
|  | am. 2011 No. 102 |
| R. 42P  | ad. 1997 No. 400 |
| R. 42Q  | ad. 1997 No. 400 |
| **Division 3** |  |
| Heading to Div. 3 of Part 6  | rs. 2000 No. 48 |
| Div. 3 of Part 6  | ad. 1997 No. 400 |
| **Subdivision 1** |  |
| Heading to Subdiv. 1 of Div. 3 of Part 6 | ad. 2000 No. 48 |
| R. 42R  | ad. 1997 No. 400 |
| R. 42S  | ad. 1997 No. 400 |
|  | am. 2000 No. 48 |
| R. 42T  | ad. 1997 No. 400 |
|  | am. 1998 No. 369; 2000 No. 48; 2002 No. 234; 2011 No. 102 |
| R. 42U  | ad. 1997 No. 400 |
|  | am. 2003 No. 361 |
| R. 42V  | ad. 1997 No. 400 |
| R. 42W  | ad. 1997 No. 400 |
|  | am. 2000 No. 48 |
| R. 42X  | ad. 1997 No. 400 |
|  | am. 2003 No. 258 |
| R. 42Y  | ad. 1997 No. 400 |
|  | am. 1998 No. 369; 2000 No. 48; 2002 Nos. 234 and 315; 2003 No. 111; 2011 No. 102 |
|  | rs. 2003 No. 301 |
| R. 42Z  | ad. 1997 No. 400 |
| R. 42ZA  | ad. 1997 No. 400 |
| R. 42ZB  | ad. 1997 No. 400 |
|  | am. 2011 No. 102 |
| R. 42ZC  | ad. 1997 No. 400 |
|  | rs. 2000 No. 48 |
| **Subdivision 2** |  |
| Subdiv. 2 of Div. 3 of Part 6  | ad. 2000 No. 48 |
| R. 42ZCAA  | ad. 2000 No. 48 |
|  | am. 2001 No. 159; 2012 No. 142 |
| Note to r. 42ZCAA  | rep. 2001 No. 159 |
| R. 42ZCAB  | ad. 2000 No. 48 |
|  | am. 2001 No. 159; 2002 No. 234; 2003 No. 301; 2004 No. 159 |
| R. 42ZCAC  | ad. 2000 No. 48 |
| R. 42ZCAD  | ad. 2000 No. 48 |
|  | am. 2002 No. 315; 2003 No. 111 |
| R. 42ZCAE  | ad. 2000 No. 48 |
| R. 42ZCAF  | ad. 2000 No. 48 |
| R. 42ZCAG  | ad. 2000 No. 48 |
| R. 42ZCAGA  | ad. 2006 No. 122 |
| R. 42ZCAH  | ad. 2000 No. 48 |
| R. 42ZCAI  | ad. 2000 No. 48 |
|  | am. 2002 Nos. 234 and 315; 2003 No. 301; 2006 No. 122; 2011 No. 102 |
| Heading to r. 42ZCAJ  | rs. 2012 No. 142 |
| R. 42ZCAJ  | ad. 2000 No. 48 |
|  | am. 2012 No. 142 |
| R. 42ZCAK  | ad. 2000 No. 48 |
| R. 42ZCAL  | ad. 2002 No. 315 |
| **Division 3A** |  |
| Div. 3A of Part 6  | ad. 1999 No. 209 |
|  | rs. 2010 No. 129 |
| **Subdivision 3A.1** |  |
| Subdiv. 1 of Div. 3A renumbered Subdiv. 3A.1 | 2010 No. 129 |
| R. 42ZCA  | ad. 1999 No. 209 |
|  | rs. 2010 No. 129 |
| **Subdivision 3A.2** |  |
| Subdiv. 2 of Div. 3A renumbered Subdiv. 3A.2 | 2010 No. 129 |
| R. 42ZCB  | ad. 1999 No. 209 |
|  | rs. 2010 No. 129 |
| R. 42ZCC  | ad. 1999 No. 209 |
|  | rs. 2010 No. 129 |
| 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** |  |
| Subdiv. 3 of Div. 3A renumbered Subdiv. 3A.3 | 2010 No. 129 |
| 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. 1999 No. 209 |
|  | rs. 2010 No. 129 |
| R. 42ZCO  | ad. 1999 No. 209 |
|  | rs. 2010 No. 129 |
| R. 42ZCP  | ad. 1999 No. 209 |
|  | rs. 2010 No. 129 |
| **Division 3B** |  |
| Div. 3B of Part 6  | ad. 2010 No. 129 |
| **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. 1999 No. 209 |
|  | rs. 2010 No. 129 |
| 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. 2010 No. 129 |
| R. 42ZCZE  | ad. 2010 No. 129 |
| R. 42ZCZF  | ad. 2010 No. 129 |
| **Division 3C** |  |
| Div. 3C of Part 6  | ad. 2010 No. 129 |
| R. 42ZCZG  | ad. 2010 No. 129 |
| R. 42ZCZH  | ad. 2010 No. 129 |
| **Division 3D** |  |
| Div. 3D of Part 6  | ad. 2010 No. 129 |
| **Subdivision 3D.1** |  |
| R. 42ZCZI  | ad. 2010 No. 129 |
| **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 |
| 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 |
| Div. 4 of Part 6  | 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 |
|  | 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 |
| Div. 5 of Part 6  | 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 |
| 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 |
|  | 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** |  |
| Heading to Part 7  | rs. 1991 No. 84; 2009 No. 141 |
| **Division 1** |  |
| Div. 1 of Part 7  | ad. 2009 No. 141 |
| **Subdivision 1** |  |
| Heading to Subdiv. 1 of Div. 1 of Part 7 | rs. 2011 No. 30 |
| R. 43AAA  | ad. 2009 No. 141 |
|  | am. 2011 No. 281 |
| **Subdivision 2** |  |
| R. 43AAB  | ad. 2009 No. 141 |
|  | rs. 2011 No. 30 |
| R. 43AAC  | ad. 2009 No. 141 |
|  | am. 2011 No. 30 |
| R. 43AAD  | ad. 2009 No. 141 |
| R. 43AAE  | ad. 2009 No. 141 |
|  | am. 2011 No. 30; 2012 No. 142 |
| R. 43AAF  | ad. 2009 No. 141 |
|  | am. 2012 No. 142 |
| R. 43AAG  | ad. 2009 No. 141 |
|  | am. 2011 No. 30 |
| R. 43AAH  | ad. 2009 No. 141 |
| R. 43AAI  | ad. 2009 No. 141 |
| **Subdivision 3** |  |
| Heading to r. 43AAJ  | rs. 2010 No. 130; 2011 No. 102 |
| R. 43AAJ  | ad. 2009 No. 141 |
|  | am. 2010 No. 130; 2011 No. 102; 2012 No. 143 |
| **Division 2** |  |
| Heading to Div. 2 of Part 7  | ad. 2009 No. 141 |
| R. 43  | am. 2003 No. 151; 2011 No. 30 |
| R. 43A  | ad. 1994 No. 222 |
|  | am. 2002 No. 234; 2011 No. 102 |
| R. 43AA  | ad. 1992 No. 19 |
|  | rs. 2011 No. 102 |
| R. 43AB  | ad. 2000 No. 267 |
| R. 45  | am. 1991 Nos. 84 and 485; 1994 Nos. 222 and 364; 1995 No. 192; 1996 No. 131; 1997 Nos. 162, 398 and 399; 1998 No. 247; 1999 No. 62; 2000 Nos. 123 and 267; 2002 No. 143; 2003 Nos. 151 and 361; 2004 No. 159; 2005 No. 192; 2006 No. 212; 2007 No. 161; 2008 No. 117; 2009 No. 179; 2010 No. 130; 2011 Nos. 30 and 102; 2012 No. 143 |
| R. 45AA  | ad. 1995 No. 192 |
|  | am. 2002 No. 234; 2011 No. 30 |
| Heading to r. 45A  | am. 1997 No. 162 |
|  | rs. 2001 No. 160; 2003 No. 151; 2004 No. 159; 2005 No. 192; 2006 No. 212; 2007 No. 161; 2008 No. 117;2009 No. 179; 2010 No. 130 |
| 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. 2012 No. 143 |
| **Part 7A** |  |
| Part 7A  | ad. 2009 No. 228 |
| R. 45B  | ad. 2009 No. 228 |
| **Part 8** |  |
| R. 46A  | ad. 1992 No. 332 |
|  | rs. 2009 No. 140 |
|  | am. 2010 No. 26 |
| 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. 1991 No. 485 |
|  | am. 1992 No. 332; 1997 No. 400; 2000 No. 48; 2001 No. 343; 2002 No. 345; 2004 No. 78; 2009 No. 228 |
| Heading to r. 47A  | rs. 2011 No. 30 |
| R. 47A  | ad. 1991 No. 485 |
|  | am. 2011 No. 30 |
| R. 47AA  | ad. 2000 No. 358 |
|  | rep. 2003 No. 361 |
| Heading to r. 47B  | am. 1999 No. 62 |
|  | 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 |
| R. 48  | am. 1991 No. 84; 1992 Nos. 332 and 430; 1995 No. 192; 1997 No. 399; 2000 No. 48; 2002 No. 234; 2003 No. 301; 2011 No. 30 |
| **Part 9** |  |
| Part 9  | ad. 2012 No. 251 |
| R. 49  | ad. 2012 No. 251 |
| **Schedule 1** |  |
| Schedule 1  | am. 1992 Nos. 89 and 332; 1994 Nos. 150 and 364; 1995 No. 208; 1997 No. 398; 1999 No. 324; 2001 No. 159; 2003 No. 258; 2006 No. 122; 2012 No. 142 |
| **Schedule 2** |  |
| Heading to Schedule 2  | rs. 2003 No. 301 |
| Schedule 2  | am. 1994 No. 150; 1995 No. 208; 1997 No. 398; 1999 No. 324; 2000 No. 48; 2001 Nos. 159 and 252; 2002 No. 234; 2006 No. 122 |
| **Schedule 3** |  |
| Schedule 3  | am. 1991 Nos. 84 and 485; 1992 Nos. 19, 89 and 370; 1994 Nos. 150 and 364; 1995 No. 208; 1997 Nos. 398 and 399; 1999 No. 62; 2002 Nos. 84, 114, 143, 234 and 315; 2004 No. 78; 2010 No. 26 |
| **Schedule 4** |  |
| Heading to Schedule 4  | am. 1998 No. 227 |
|  | rs. 2002 No. 234 |
| Schedule 4  | am. 1991 No. 84; 1992 Nos. 19 and 89; 1994 No. 150; 1995 Nos. 208 and 320; 1996 Nos. 9 and 208; 1997 No. 398; 1998 Nos. 227 and 369; 1999 Nos. 62 and 324; 2000 No. 48; 2001 Nos. 159 and 252; 2002 Nos. 84, 114, 234 and 315; 2003 Nos. 258 and 361; 2004 Nos. 78 and 127; 2010 No. 26; 2011 Nos. 30 and 281; 2012 No. 251 |
| **Schedule 5** |  |
| Heading to Schedule 5  | 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 |
| **Schedule 5A** |  |
| Heading to Schedule 5A  | am. 2002 No. 234 |
|  | rs. 2011 No. 30; 2012 No. 251 |
| Schedule 5A  | ad. 1991 No. 84 |
|  | am. 1992 No. 89; 1994 Nos. 150 and 364; 1995 Nos. 33 and 208; 1996 No. 9; 1997 No. 399; 1999 No. 62; 2000 No. 358; 2001 Nos. 159 and 343; 2002 Nos. 84 and 345; 2003 No. 111; 2004 No. 78; 2010 No. 26; 2011 No. 30 |
| **Schedule 5B** |  |
| Heading to Schedule 5B  | rs. 2011 No. 30 |
| Schedule 5B  | ad. 2003 No. 111 |
|  | am. 2010 No. 266; 2011 No. 30 |
| **Schedule 6** |  |
| Schedule 6  | am. 1992 Nos. 19, 89 and 370; 1994 No. 150; 1995 No. 208; 1997 No. 398; 1999 No. 324; 2010 No. 26 |
| **Schedule 7** |  |
| Heading to Schedule 7  | am. 2002 No. 234 |
| Schedule 7  | am. 1991 No. 84; 1992 Nos. 19, 89 and 370; 1994 No. 150; 1995 No. 208; 1997 No. 398; 1998 No. 227; 1999 No. 324; 2000 No. 124; 2001 No. 159; 2010 No. 26; 2012 No. 251 |
| **Schedule 8** |  |
| Heading to Schedule 8  | am. 2002 No. 234 |
| Schedule 8  | am. 1992 No. 89; 1994 No. 150; 1997 No. 398; 1999 No. 62; 2011 No. 30 |
| **Schedule 9** |  |
| Heading to Schedule 9  | rs. 2011 No. 30 |
| 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 |
| **Schedule 9A** |  |
| Schedule 9A  | ad. 2011 No. 30 |
|  | am. 2012 No. 143 |
| **Schedule 10** |  |
| Heading to Schedule 10  | rs. 1992 Nos. 332 and 370 |
|  | am. 1995 No. 208 |
| Schedule 10  | ad. 1992 No. 19 |
|  | am. 1992 No. 89; 1994 No. 150; 1995 No. 208 |
|  | rs. 1998 No. 227 |
|  | am. 1999 No. 62; 2000 No. 29; 2004 No. 78; 2010 No. 26; 2011 No. 102 |
| 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 |
| **Schedule 13** |  |
| Schedule 13  | ad. 1995 No. 208 |
|  | am. 2001 No. 159; 2003 No. 151; 2011 No. 102 |
| **Schedule 14** |  |
| Heading to Schedule 14  | am. 1999 No. 62 |
|  | rs. 2011 No. 102 |
| Schedule 14  | ad. 1997 No. 400 |
|  | rs. 1998 No. 227 |
| **Schedule 15** |  |
| Schedule 15  | ad. 2009 No. 228 |
| **Schedule 16** |  |
| Schedule 16  | ad. 2011 No. 30 |

Table A Application, saving or transitional provisions

Statutory Rules 1994 No. 150

22. Date of effect of revocation of exemptions

 2.1 For the purposes of subsections 18 (3) and 34 (3) of the *Therapeutic Goods Act 1989*, the revocations of exemptions made by subregulations 15.6, 17.2, 18.2 and 18.3 of these Regulations take effect on 1 July 1994.

Statutory Rules 1995 No. 208

19. Transitional provisions

 19.1 If:

 (a) an application is made under section 23 of the Act in relation to therapeutic goods to which paragraph (d) or subparagraph (l) (ii) of item 7 in Schedule 5 to the Therapeutic Goods Regulations, as in force immediately before 4 July 1995; and

 (b) the application is made in the period from the beginning of 4 July 1995 to the end of 31 December 1995;

Part 3 of the Act applies to those goods as if subregulations 10.5, 11.2 and 11.4 of these Regulations had not commenced until the application is decided.

 19.2 If:

 (a) an application is made under section 23 of the Act in relation to therapeutic goods to which paragraphs (a) and (g) of item 8 in Schedule 5 to the Therapeutic Goods Regulations, as in force immediately before 4 July 1995; and

 (b) the application is made in the period from the beginning of 4 July 1995 to the end of 30 September 1995;

Part 3 of the Act applies to those goods as if subregulations 10.3, 11.5 and 11.8 of these Regulations had not commenced until the application is decided.

Statutory Rules 1999 No. 209

**4 Transitional**

 (1) For the first meeting of the National Drugs and Poisons Schedule Committee:

 (a) a quorum is 5 jurisdictional members; and

 (b) the public consultation procedures set out in subdivision 5 of Division 3A of Part 6 of the principal Regulations do not apply.

 (2) At that meeting, the Committee must make decisions in relation to the classification and scheduling of all substances in relation to which a decision of that kind has been made by AHMAC that does not form part of the first Poisons Standard because the AHMAC decision:

 (a) was made on or after 1 April 1999; or

 (b) was made before 1 April 1999 but had not been published as part of the first Poisons Standard.

 (3) In making a decision about a substance mentioned in subregulation (2) , the Committee:

 (a) may, for subsection 52E (1) of the Act, accept the findings of AHMAC about a matter mentioned in that subsection in connection with that substance; and

 (b) must take account of the scheduling decision of AHMAC for that substance and the consequences a Committee decision at variance with the AHMAC decision would have for industry and the community.

 (4) A word or expression used in subregulation (2) and in section 52A of the Act has the same meaning in that subregulation as it has in that section.

 (5) In this Regulation:

***Act*** means the *Therapeutic Goods Act 1989*.

***AHMAC*** means the Australian Health Ministers’ Advisory Council and includes a subcommittee of the Council acting on the Council’s behalf.

***jurisdictional member*** has the meaning given by regulation 42ZCE of the principal Regulations.

***principal Regulations*** means the *Therapeutic Goods Regulations 1990*.

Statutory Rules 2004 No. 127

4 Transitional

 Despite the amendments made by these Regulations, the *Therapeutic Goods Regulations 1990*, as in force immediately before the commencement of these Regulations (the ***commencement time***), continue to apply for a period of 12 months after the commencement time in relation to therapeutic goods that, immediately before the commencement time, were registered goods or listed goods.

Select Legislative Instrument 2009 No. 374

4 Transitional

 (1) These Regulations apply to a person who is a member or associate member of a committee mentioned in column 2 of the following table (the ***old committee***), as if the person was a member of the corresponding committee mentioned in column 3 of the table (the ***new committee***) until:

 (a) the term of that person’s current appointment to the old committee expires; or

 (b) the person resigns from the new committee; or

 (c) the person is removed from the new committee.

| Item | Old Committee | New Committee |
| --- | --- | --- |
| 1 | Australian Drug Evaluation Committee | Advisory Committee on Prescription Medicines |
| 2 | Medicines Evaluation Committee | Advisory Committee on Non‑prescription Medicines |
| 3 | Complementary Medicines Evaluation Committee | Advisory Committee on Complementary Medicines |
| 4 | Medical Devices Evaluation Committee | Advisory Committee on Medical Devices |

 (2) A request for advice by, or referred by, the Minister or the Secretary to the old committee is taken to be a request for advice to the new committee if:

 (a) the request is referred to the old committee before the establishment of the new committee; and

 (b) the advice has not been given by the old committee.

 (3) In considering a request for advice mentioned in subregulation (2), the new committee must take into account any relevant considerations or recommendations of the old committee.

 (4) Recommendations, evaluations or assessments made by the old committee or a subcommittee of the old committee must be taken into account by the new committee if:

 (a) the recommendations, evaluations or assessments were made before the establishment of the new committee; and

 (b) the recommendations, evaluations or assessments were not formally given to the Minister or the Secretary.

 (5) A request for advice on the safety of a medicine to the Adverse Drug Reactions Advisory Committee is taken to be a request for advice to the Advisory Committee on the Safety of Medicines if:

 (a) the request is referred to the Adverse Drug Reactions Advisory Committee before the establishment of the Advisory Committee on the Safety of Medicines; and

 (b) the advice has not been given by the Adverse Drug Reactions Advisory Committee.

 (6) In considering a request for advice mentioned in subregulation (5), the Advisory Committee on the Safety of Medicines must take into account any relevant considerations or recommendations of the Adverse Drug Reactions Advisory Committee.

 (7) Recommendations, evaluations or assessments made by the Adverse Drug Reactions Advisory Committee on the safety of a medicine must be taken into account by the Advisory Committee on the Safety of Medicines if they:

 (a) were made before the establishment of the Advisory Committee on the Safety of Medicines; and

 (b) were not formally given to the Minister or the Secretary.

 (8) In this regulation:

***Adverse Drug Reactions Advisory Committee*** means the subcommittee of that name appointed by the Australian Drug Evaluation Committee under subregulation 36 (6) of the *Therapeutic Goods Regulations 1990* as in force on 31 December 2009.

***Advisory Committee on Complementary Medicines*** means the committee established under regulation 39 of the *Therapeutic Goods Regulations 1990* as in force on 25 January 2010.

***Advisory Committee on Medical Devices*** means the committee established under regulation 38 of the *Therapeutic Goods Regulations 1990* as in force on 1 January 2010.

***Advisory Committee on Non-prescription Medicines*** means the committee established under regulation 36 of the *Therapeutic Goods Regulations 1990* as in force on 1 January 2010.

***Advisory Committee on Prescription Medicines*** means the committee established under regulation 35 of the *Therapeutic Goods Regulations 1990* as in force on 1 January 2010.

***Advisory Committee on the Safety of Medicines*** means the committee established under regulation 37 of the *Therapeutic Goods Regulations 1990* as in force on 1 January 2010.

***Australian Drug Evaluation Committee*** means the committee established under subregulation 36 (1) of the *Therapeutic Goods Regulations 1990* as in force on 31 December 2009.

***Complementary Medicines Evaluation Committee*** means the committee established under subsection 52G (1) of the *Therapeutic Goods Act 1989* as in force on 31 December 2009.

***Medical Devices Evaluation Committee*** means the committee established under subregulation 35 (1) of the *Therapeutic Goods Regulations 1990* as in force on 31 December 2009.

***Medicines Evaluation Committee*** means the committee of that name established under subregulation 42ZZB (1) of the *Therapeutic Goods Regulations 1990* as in force on 31 December 2009.

Select Legislative Instrument 2010 No. 26

4 Definitions for transitional provisions

 In regulations 5, 6 and 7:

***Act*** means the *Therapeutic Goods Act 1989*.

***in-house IVD medical device*** has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002* as in force on 1 July 2010.

***IVD medical device*** has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002* as in force on 1 July 2010.

5 Transitional — certain devices

 (1) This regulation applies to a diagnostic good for in vitro use that, immediately before 1 July 2010:

 (a) was declared not to be a medical device under subsection 41BD (3) of the Act; and

 (b) was:

 (i) listed or registered under Part 3-2 of the Act; or

 (ii) subject to an approval under paragraph 19 (1) (b) of the Act; or

 (iii) exempt from listing or registration under Part 3-2 of the Act; or

 (iv) a device for which an effective application for listing or registration under Part 3-2 of the Act had been made but not finally determined.

*Note*   For circumstances in which an application under Part 3-2 of the Act is effective, see subsection 23 (2) of the Act.

 (2) The listing or registration under Part 3-2 of the Act of a device mentioned in subparagraph (1) (b) (i) or (iv) is taken to be cancelled on:

 (a) if no effective application for including the device in the Register under Chapter 4 of the Act has been made before 1 July 2014 — 1 July 2014; or

 (b) the day when inclusion of the device in the Register under Chapter 4 of the Act takes effect following an effective application made for the inclusion of the device in the Register under that Chapter.

 (3) Despite the amendments made by Schedule 1, a device mentioned in paragraph (1) (b) (iii) that was exempt from the requirements for registration or listing under Part 3-2 of the Act immediately before 1 July 2010 remains exempt until 30 June 2014.

 (4) The amendments made by Schedule 1 do not apply to each of the following diagnostic goods for in vitro use that, immediately before 1 July 2010, was declared not to be a medical device under subsection 41BD (3) of the Act, until the exemption that applies to the goods immediately before 1 July 2010 ceases to have effect:

 (a) a device that was exempt from listing or registration under Part 3-2 of the Act because item 3 of Schedule 5A to the *Therapeutic Goods Regulations 1990* applies to it;

 (b) a device mentioned in subparagraph (1) (b) (ii);

 (c) a device for which an application under paragraph 19 (1) (b) of the Act had been made but not finally determined.

 (5) For subparagraph (1) (b) (iv) and paragraph (4) (c), an application is finally determined at the first time both the following conditions are met:

 (a) a decision has been made whether to grant the application;

 (b) there is no longer any possibility of a change in the outcome of the decision in terms of the granting of the approval for the import, export or supply, or the listing or registration of the device.

 (6) For paragraph (5) (b), the possibility of a discretion being exercised after the period has ended, to extend the period for seeking review by a court or tribunal of the decision or of starting other proceedings (including appeals) arising out of the application, decision or review, is not to be considered.

6 Transitional — in-house IVD medical devices

 The amendments made by Schedule 1 apply to an in-house IVD medical device after 30 June 2014.

7 Transitional — other devices

 The amendments made by Schedule 1 apply to any good or device that is not mentioned in regulation 5 or 6 after 30 June 2010.

Select Legislative Instrument 2010 No. 266

4 Transitional

 (1) This regulation applies if:

 (a) a person is given a notice under regulation 12AAA of the *Therapeutic Goods Regulations 1990* before the day these Regulations commence (the ***commencement day***); and

 (b) the person has not complied with clause 1 of Schedule 5B of the *Therapeutic Goods Regulations 1990* before the commencement day.

 (2) Despite the repeal of regulation 12AAA and amendment of clause 1 by these Regulations, the person must comply with clause 1 as if it had not been amended by these Regulations.