Therapeutic Goods Regulations 1990

Statutory Rules 1990 No. 394 as amended

made under the

Therapeutic Goods Act 1989

This compilation was prepared on 1 October 2004
taking into account amendments up to SR 2004 No. 159

Prepared by the Office of Legislative Drafting,
Attorney-General's Department, Canberra

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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 implantable therapeutic device:

(a) means an active therapeutic device designed for implantation, totally or partially, into the human body:

(i) surgically; or

(ii) by other medical intervention, into a natural orifice; and

(b) includes an accessory designed for use with the device.

active ingredient has the same meaning as in section 52F of the Act.

active therapeutic device means a device that relies for its functioning on a source of electrical energy or any other source of power that is not generated directly by the human body or by gravity.

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.

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

complementary medicines has the same meaning as in section 52F of the Act.

Complementary Medicines Evaluation Committee means the Committee established under subsection 52G (1) of the Act.

critical medical device means a device that, when used as recommended by its manufacturer, is in a sterile condition on introduction into the human body.

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.

diagnostic goods for in vitro use means any therapeutic device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination (with other diagnostic goods for *in vitro* use), intended by the manufacturer to be used *in vitro* for the examination of specimens (including blood and tissue donations) derived from the human body, solely or principally for the purpose of giving information about a physiological or pathological state or a congenital abnormality or to determine safety and compatibility with a potential recipient.

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.

generic medicine means a medicine that, in comparison to a registered medicine:

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

(b) has the same pharmaceutical form; and

(c) is bioequivalent; and

(d) has the same safety and efficacy properties.

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

goods for home use, in relation to diagnostic goods for *in vitro* use, means goods supplied to a person for that person:

(a) to use in diagnosing or monitoring a condition in that person or the immediate family of that person; or

(b) to use in the collection of a sample of a body specimen of that person and, if the sample is tested by another person, if and only if the results of the test are to be returned by

that other person to the person from whom the sample was taken.

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:

(a) kills all microbial pathogens, except bacterial endospores, when used as recommended by its manufacturer; and

(b) is the minimum treatment recommended by the manufacturer of a semi critical medical device for the reprocessing of the device.

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.

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.

implantable, in relation to a therapeutic device, means designed to be implanted into the tissues or body cavities of a person or animal, other than in the teeth, for a period of 30 days or more.

instrument grade disinfectant means:

(a) a high level disinfectant; or

(b) a sterilant;

that is used to reprocess reusable semi critical or critical medical devices.

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.

non critical medical device means a device that, when used as recommended by its manufacturer:

(a) does not ordinarily contact the human body; or

(b) if contact with the human body is made — contacts only healthy intact skin.

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.

semi critical medical device means a device that, when used as recommended by its manufacturer:

(a) makes contact with healthy intact mucous membranes of the human body; and

(b) does not ordinarily enter normally sterile areas of the body.

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 the Standards Australia International Limited and the body known as Standards New Zealand.

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 known as the Therapeutic Goods Advertising Code as in force from time to time.

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 has the same meaning as in section 52F of the Act.

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

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 Definitions of ***medicine*** and ***poison*** are in the Act (see subsection 3 (1)).

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*.

(2) For the definition of ***corresponding State law*** in subsection 3 (1) of the Act, the **Therapeutic Goods (Victoria) Act 1994** is declared to correspond to the Act.

(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 2002* (NSW);

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

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

3A Unacceptable presentations

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.

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 approve or refuse to approve advertisements 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 to approve or refuse to approve 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 following powers of the Secretary under regulation 5G:

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

(b) the power to approve or refuse to approve 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 5L to withdraw the approval of a class of approved advertisements to a person to whom the Secretary has delegated the power to approve 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.

6A Approval of use of restricted representation — public interest criteria [*see* Note 2]

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 clauses 4.1, 4.2, 4.3 and 4.4 of Part 4 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 clauses 4.1, 4.2, 4.3 and 4.4 of Part 4 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.

product information, in relation to therapeutic goods, has the meaning given by subsection 9D (5) of the Act.

(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) If goods (other than medical devices) that are included in the part of the Register for listed goods become subject to inclusion in the part of the Register for registered goods, the person in whose name the goods are entered in the Register

must apply to the Secretary to transfer the entry in relation to the goods to the part of the Register for registered goods.

(2) An application under subregulation (1) 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 — not later than 15 months after the day on which the goods became subject to inclusion in the part of the Register for registered goods.

Penalty: 5 penalty units.

(2A) An offence under subregulation (2) is an offence of strict liability.

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

(3) In determining a period of notice for the purposes of paragraph (2) (a) the Secretary is to have regard to:

(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.

(4) It is not an offence for the sponsor of goods to which subregulation (1) applies to import, export, supply or manufacture the goods as listed goods until the time for making the application under subregulation (2) has expired or, if an application is made, until it is determined, whichever is the later.

(5) 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 in relation to 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.

(6) If:

(a) goods are included in the Register under Chapter 4 as a kind of medical device; and

(b) the goods cease to be a medical device because of a declaration under subsection 41BD (3) of the Act;

the person in relation to whom the kind of device is included in the Register may apply to the Secretary to transfer the entry in relation to the goods to the part of the Register for registered goods or the part of the Register for listed goods, as the case requires.

(7) An application to transfer an entry in relation to goods from a part of the Register to the part of the Register for registered goods, or the part of the Register for listed goods, is to be treated as an application for registration or listing of the goods, as the case requires.

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.

(5) If a person notifies the Secretary of an event under paragraph (1) (b), (2) (b) or (3) (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*.

Part 3 Registration, 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.

12 Exempt goods

(1) For the purposes of subsection 18 (1) of the Act, the therapeutic goods or classes of therapeutic goods specified in Schedule 5 are exempt from the operation of Part 3-2 of the Act (except sections 30EA, 31A and 31C to 31F).

(1AA) For the purposes of item 7 in Schedule 5, a device or part of a device:

(a) is powered if the whole or part of the energy applied to it comes from a source other than the application of human energy; and

(b) is non-powered if paragraph (a) does not apply.

(1A) For the purposes of subsection 18 (1) of the Act, the therapeutic goods or classes of therapeutic goods specified in an item in column 2 of Schedule 5A are exempt from the operation of Part 3-2 of the Act (except sections 30EA, 31A and 31C to 31F) subject to compliance with the relevant conditions specified in column 3 of that Schedule.

(2) If:

(a) therapeutic goods that, in relation to a provision of Part 3-2 of the Act, are exempt goods cease to be exempt goods; and

(b) the sponsor of the goods has applied for registration or listing of the goods before the goods cease to be exempt goods;

the goods are taken to be exempt goods until the application for registration or listing is determined.

12A Unapproved medicines — 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).

(2) The exemption of a medicine is subject to the following conditions:

(a) the medicine 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 being given to the person; and

(iii) the medical practitioner by whom, or at whose direction, the medicine 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 is dispensed on the prescription of a medical practitioner who has prescribed the medicine 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.

12AAA Emergency goods — early cessation of exemption

(1) This regulation applies to:

(a) a revocation, under paragraph 18A (4) (b) of the Act, of an exemption of therapeutic goods under subsection 18A (1) of the Act; and

(b) a variation, under paragraph 18A (5) (b) of the Act, of an exemption under subsection 18A (1) of the Act, that removes particular therapeutic goods from the exemption.

(2) The Secretary must give notice of the revocation or variation to persons who, under the exemption, have been importing, manufacturing, supplying or exporting the goods by:

(a) writing to the person; or

(b) publication in the *Gazette.*

(3) A notice given under subregulation (2) must:

(a) identify the goods covered by the revocation or variation; and

(b) state the date that the exemption ceases to have effect for the goods.

12AAB Disposal of unused emergency goods

(1) For subsection 30G (2) of the Act, Schedule 5B sets out the requirements of, and in relation to, an arrangement for disposal of unused emergency goods.

(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.

12AA Applications for special and experimental uses

Without limiting the information that may be required by the Secretary under subsection 19 (2) of the Act, that information may include, in relation to therapeutic goods the subject of an application under subsection 19 (1) of the Act for a use described in paragraph 19 (1) (b) 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 subsection 19 (1A) 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 subsection 19 (4A) 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

(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 Application of Part 3-2 to medical devices (Act s 15A)

For subparagraph 15A (5) (a) (ii) of the Act, a kind of medical device is specified if:

(a) it is a medical device of a kind that is manufactured in Australia by a person mentioned in column 2 of Schedule 8, as in force immediately before the commencement of the *Therapeutic Goods Amendment (Medical Devices) Act 2002*; and

(b) it is manufactured in the circumstances set out in column 3 of that Schedule, as in force immediately before that commencement.

Note Schedule 8 identifies persons who are exempt from the operation of Part 3-3 of the *Therapeutic Goods Act 1989* in relation to the manufacture or a step in the manufacture of therapeutic goods or a class of therapeutic goods — see subsection 34 (2) of the Act and regulation 18.

15 Application of registration or listing number to goods

(1) For the purposes of paragraph 20 (2) (a) 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 of therapeutic goods

(1) For the purposes of paragraph 28 (5) (e) of the Act, a person to whom the registration of a therapeutic good specified in Part 1 of Schedule 10 relates must comply with the reporting requirements set out in the document entitled 'Australian Guideline For Pharmacovigilance Responsibilities Of Sponsors Of Registered Medicines Regulated By Drug Safety And Evaluation Branch' published by the Therapeutic Goods Administration, as in force from time to time.

(2) For the purposes of subregulation (1), a reference to a registered medicine or a registered medicinal product in the document mentioned in that subregulation is taken to be a reference to a therapeutic good.

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.

(2) For the purposes of paragraph 26 (1) (k) of the Act, the criteria stated in Part 2 of Schedule 11 are prescribed for therapeutic goods of the kinds stated in Part 1 of that Schedule.

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.

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

(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.

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 6 Committees

Division 1 Therapeutic Goods Committee, Medical Devices Evaluation Committee and Australian Drug Evaluation Committee

34 Therapeutic Goods Committee

(1) The Therapeutic Goods Committee is established.

(2) The Committee's functions are:

(a) to consider:

(i) the adoption of standards for therapeutic goods; and

(ii) matters relating to standards for therapeutic goods; and

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

(iv) principles to be observed in the manufacture of therapeutic goods for human use; and

(v) matters relating to the adequacy of a medical device standard in so far as it relates to a part or parts of the essential principles; and

(vi) matters relating to the adequacy of a conformity assessment standard in so far as it relates to a part or parts of the conformity assessment procedures;

and advise the Minister of the results of its consideration; and

(b) to advise the Minister on the likely impact that adoption of a proposed standard would have on Australian domestic and international trade; and

(c) to consider a matter that is referred to the Committee by the Minister and to advise the Minister of the results of its consideration.

(3) The Committee must:

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

(b) when considering a matter to which paragraph (2) (a) applies, have regard to:

(i) the desirability of adopting standards of the British Pharmacopoeia and 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.

(4) The Minister must appoint in writing 11 persons to the Committee in accordance with subregulations (4A), (4B) and (4C).

(4A) The Committee must comprise the following persons:

(a) a person who is nominated to the Minister in writing by a body that represents, or a combination of bodies that together represent, the interests of Australian manufacturers of prescription medicine products;

(b) a person who is nominated to the Minister in writing by a body that represents, or a combination of bodies that together represent, the interests of Australian manufacturers of non-prescription medicine products;

(c) a person who is nominated to the Minister in writing by a body that represents, or a combination of bodies that together represent, the interests of Australian manufacturers of alternative medicines;

(d) a person who is nominated to the Minister in writing by a body that represents, or a combination of bodies that together represent, the interests of Australian manufacturers of medical devices and other therapeutic goods;

(e) a person who is nominated to the Minister in writing by a body that represents, or a combination of bodies that together represent, the interests of consumers of health services;

(f) a person with expertise in microbiology and virology;

(g) a person with expertise in biomedical engineering;

(h) a person with expertise in the biological safety of biomaterials;

(i) a person with expertise in biotechnology;

(j) a person with expertise in pharmaceutical sciences;

(k) a member of the Health and Food Standards Advisory Committee of Standards Australia.

(4B) At least 1 of the persons appointed to the Committee must be a medical practitioner.

(4C) At least 1 of the persons to whom paragraphs (4A) (f), (g), (h), (i), (j) and (k) refer must be able to represent the interests of consumers of health services.

(4D) The chairperson of the Committee may invite a person who is nominated in writing by the National Registration Authority for Agricultural and Veterinary Chemicals to attend a meeting at which a matter that is relevant to the function of the Authority is to be discussed.

(5) The Minister is to appoint, in writing, a member of the Committee to be its chairperson.

(6) The Committee may appoint sub-committees, consisting of members of the Committee and other persons to inquire into, and report to the Committee on, any matter that is within the functions of the Committee.

35 Medical Devices Evaluation Committee

(1) The Medical Devices Evaluation Committee is established.

(2) The functions of the Committee are:

(a) to give medical and scientific advice to the Minister or the Secretary in relation to any medical device that the Minister or the Secretary refers to it; and

(b) to give medical and scientific advice to the Minister or the Secretary in relation to any medicines that the Minister or the Secretary refers to it; and

(c) to give medical and scientific advice to the Minister or the Secretary in relation to any other therapeutic goods that the Minister or the Secretary refers to it; and

(d) to give advice to the Minister or the Secretary about the importation into, exportation from, and manufacture, distribution and supply in Australia, of therapeutic goods that have been assessed by the Committee; and

(e) to give advice that has been given to the Minister or the Secretary under paragraph (d) to persons or bodies as the Minister may direct.

(3) Membership of the Committee consists of:

(a) at least 8, and not more than 12, core members; and

(b) at least 8, and not more than 20, associate members.

(4) The Minister must appoint to the Committee:

(a) as core members:

(i) at least 3 persons, each of whom is a medical practitioner eminent in the medical profession and at least 2 of whom are specialists in clinical medicine; and

(ii) at least 1 person with expertise in consumer issues; and

(iii) at least 1 person with expertise in industry issues; and

(iv) at least 1 person who is a biomedical engineer, or who holds a university degree in biomedical engineering; and

(v) at least 1 person with expertise in biomaterials, or who holds a university degree in biomaterial science; and

(b) as associate members:

(i) at least 1 person who is a medical practitioner eminent in the medical profession; and

(ii) at least 1 person who is a biomedical engineer, or who holds a university degree in biomedical engineering; and

(iii) at least 1 person with expertise in biomaterials, or who holds a university degree in biomaterial science.

(5) The Minister must appoint, in writing, a member of the Committee to be its chairperson.

(6) The Committee may appoint sub-committees, consisting of members of the Committee and other persons, to inquire into, and report to the Committee on, any matter within the Committee's functions.

36 Australian Drug Evaluation Committee

(1) The Australian Drug Evaluation Committee is established.

(2) The functions of the Committee are:

(a) to make medical and scientific evaluations of any medicines that the Minister or the Secretary refers to it for evaluation; and

(b) to make medical and scientific evaluations of other medicines if, in the opinion of the Committee, it is desirable that it should do so; and

(c) to make medical and scientific evaluations of such medical devices and other therapeutic goods that the Minister or the Secretary refers to it for evaluation; and

(d) to give advice to the Minister or the Secretary about the importation into, the exportation from and the manufacture and distribution within, Australia of therapeutic goods that have been the subject of evaluation by the Committee; and

(e) to give advice that has been given to the Minister or the Secretary under paragraph (d) to persons or bodies as the Minister may direct.

(3) Membership of the Committee consists of:

(a) 6 or 7 core members; and

(b) at least 10, and not more than 20, associate members.

(4) The Minister must appoint to the Committee:

(a) as core members:

(i) at least 3 persons, each of whom is a medical practitioner eminent in the medical profession and at least 2 of whom are specialists in clinical medicine; and

(ii) at least 1 person who is a pharmacologist, or who holds a university degree in science or a branch of science and has specialised in pharmaceutical science; and

(b) as associate members:

(i) at least 1 person who is a pharmaceutical chemist with recent experience in the manufacturing of therapeutic goods; and

(ii) at least 1 person who is a toxicologist; and

(iii) at least 1 person who is a medical practitioner currently engaged in general practice; and

(iv) other persons, each of whom:

(A) satisfies a criterion set out in subparagraph (i), (ii) or (iii); or

(B) is a medical practitioner with specialist qualifications and experience in a field of medicine that complements the expertise of core members with medical qualifications.

(5) The Minister is to appoint, in writing, a member of the Committee to be its chairperson.

(6) The Committee may appoint sub-committees, consisting of members of the Committee and other persons, to inquire into, and report to the Committee on, any matter that is within the functions of the Committee.

37 Minister or Secretary may seek further advice

Where a Committee established under this Division gives advice to the Minister or the Secretary, the Minister or the Secretary may send a copy of that advice to another Committee established under this Division and that other Committee may make comments to the Minister or the Secretary in relation to that advice as it thinks fit.

38 Tenure of office of members

(1) Subject to subregulation (3), a member of a Committee established under this Division, other than the Australian Drug Evaluation Committee, holds office for a term not exceeding 3 years.

(1A) Subject to subregulation (3):

(a) a core member of the Australian Drug Evaluation Committee holds office for a term not exceeding 3 years; and

(b) an associate member of that Committee holds office for a term not exceeding 5 years.

(2) Subject to subregulation (2A), a member of a Committee established under this Division is eligible for re-appointment.

(2A) A person is not eligible to serve as a member of the Medical Devices Evaluation Committee or as a core member of the Australian Drug Evaluation Committee:

(a) for more than 3 consecutive terms; or

(b) for more than 5 terms in all.

(3) The Minister may, for reasons of misbehaviour, physical or mental incapacity, bankruptcy or imprisonment, by instrument, remove a member from office at any time.

39 Disclosure of interest

(1) A member of a Committee established under this Division who has a direct or indirect pecuniary interest in a matter being considered or about to be considered at a meeting of the Committee 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 Committee.

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

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

(b) take part in any decision of the Committee 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 pecuniary interest in the matter to which the disclosure relates must not:

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

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

40 Acting members

(1) The Minister may appoint a person to act as a member of a Committee established under this Division:

(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 from Australia or is, for any other reason, unable to perform the duties of the office.

(2) A person appointed to act during a vacancy in the office of a member must not continue so to act for more than 12 months.

(3) Anything done by a person purporting to act as a member is not invalid merely because:

(a) the occasion for the appointment had not arisen; or

(b) there is a defect or irregularity in connection with the person's appointment; or

(c) the appointment had ceased to have effect; or

(d) the occasion for the person to act had not arisen or had ceased.

41 Meetings of Committees

(1) Meetings of a Committee established under this Division are to be held at the times and places that the chairperson of the Committee directs.

(2) At a meeting of a Committee:

(a) in the case of the Therapeutic Goods Committee — 5 members constitute a quorum; and

(b) in the case of the Australian Drug Evaluation Committee — 6 members, of whom at least 3 are core members, constitute a quorum; and

(c) in the case of the Medical Devices Evaluation Committee — 6 members, of whom at least 4 are core members, constitute a quorum.

(2A) An associate member of the Australian Drug Evaluation Committee, or the Medical Devices Evaluation Committee, is eligible to attend a meeting of the relevant Committee only at the invitation of the chairperson of that Committee.

(2B) The Australian Drug Evaluation Committee may delegate to the chairperson of the Committee any function of the Committee.

(2C) The Medical Devices Evaluation Committee may delegate to the chairperson of the Committee any function of the Committee.

(3) The chairperson of a Committee is to preside at all meetings of the Committee at which he or she is present.

(4) If the chairperson of a Committee is absent from a meeting of a Committee, the members of the Committee present are to appoint one of their number to preside at that meeting.

(5) A question arising at a meeting of a Committee is to be determined by a majority of votes of the members present and voting.

(6) The member presiding at a meeting of a Committee has a deliberative vote and, in the event of an equality of votes, also has a casting vote.

42 Effect of vacancy on Committees

The exercise of a power or the performance of a function of a Committee established under this Division is not affected by a vacancy or vacancies in the membership of that 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 13 members as follows:

(a) 4 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;

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

(i) the Australian Association of National Advertisers;

(ii) the Advertising Federation 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;

(e) 1 government member and 1 other member, both nominated by the Therapeutic Goods Administration.

(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) the Cosmetics, Toiletries and Fragrances Association of Australia; and

(c) the Medical Industries Association of Australia; and

(ca) Medicines Australia; and

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

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

(2B) For subregulation (2A), the pairs of bodies are:

(a) Commercial Television Australia and Commercial Radio Australia Limited; and

(b) the Australian Publishers Bureau and the Outdoor Advertising Association of Australia.

(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 pecuniary interest 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 pecuniary interest 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 8 members, as follows:

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

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

(i) the CHCA;

(ii) the ASMI;

(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 must nominate an additional member for a meeting of the Panel at which a complaint about a medical device or other therapeutic goods 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 4 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 subregulations (2) and (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.

(2) If a complaint about a medical device or other therapeutic goods is to be considered at a meeting of the Panel, the quorum must include the member nominated under subregulation 42T (1A) for that meeting.

(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 pecuniary interest 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 pecuniary interest 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:

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 responsible or 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.

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

request is made, 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;

(b) cancel the registration or listing of the goods under paragraph 30 (2) (e) 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 Panel not to deal with complaint if court proceedings begun

(1) The Panel cannot 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 cannot deal with the complaint until the proceeding is finally disposed of.

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 National Drugs and Poisons Schedule Committee

Subdivision 1 Preliminary

42ZCA Definitions for Division 3A

In this Division:

Committee means the National Drugs and Poisons Schedule Committee.

Note The Committee is established by s 52B of the Act.

jurisdictional member has the meaning given by regulation 42ZCE.

Subdivision 2 Functions of Committee

42ZCB Committee may establish subcommittees

(1) To assist in the performance of its functions, the Committee may, with the approval of the National Manager of the Therapeutic Goods Administration, appoint subcommittees, comprising at least 1 member of the Committee and other persons with appropriate expertise and experience.

(2) The function of a subcommittee is to inquire into, and report to the Committee on, any matter, within the functions of the Committee, that is referred to it by the Committee.

(3) A subcommittee may make recommendations to the Committee.

Note Section 52C of the Act sets out the functions of the Committee.

Subdivision 3 Constitution of Committee

42ZCC Membership of Committee

The Committee is constituted in accordance with this Subdivision.

42ZCD Committee members

(1) The Committee comprises each jurisdictional member and other persons appointed by the Minister under this regulation.

(2) The Minister may appoint as a member an expert or a representative.

(3) Each of the following persons is an ***expert***:

(a) a medical practitioner expert in clinical pharmacology;

(b) an expert in veterinary medicine or pathology;

(c) an expert in toxicology;

(d) an expert in occupational health.

(4) Each of the following persons is a ***representative***:

(a) a person nominated by the Therapeutic Goods Administration;

(b) a person nominated by the National Registration Authority for Agricultural and Veterinary Chemicals;

(c) a person nominated by an agency of the New Zealand government responsible for the regulation of medicines for human use;

(d) a person nominated by an agency of the New Zealand government responsible for the regulation of agricultural, veterinary and household chemicals;

(e) a person whom the Minister is satisfied represents the pharmaceutical, chemical, agricultural and veterinary industries;

(f) a person whom the Minister is satisfied represents practising pharmacists;

(g) a person whom the Minister is satisfied represents consumers.

(5) For each category mentioned in subregulation (4), 1 representative only may be appointed.

42ZCE Jurisdictional members

The following persons are jurisdictional members of the Committee:

(a) each representative nominated under subsection 52B (3) of the Act;

(b) each of the persons appointed as a representative under paragraph 42ZCD (4) (c) or (d).

Note Only one of the persons appointed as a representative under para 42ZCD (4) (c) or (d) is counted as a jurisdictional member for r 42ZCQ and 42ZCR.

42ZCF Appointment to be in writing

An appointment of a Committee member must be in writing.

42ZCG Appointment of Chair

The Minister must appoint a Committee member who is a Commonwealth officer to be the chair of the Committee.

Note Committee members who could be Commonwealth officers are the persons mentioned in para 42ZCD (4) (a) and (b) and the representative nominated by the Commonwealth under subs 52B (3) of the Act.

42ZCH Term of appointment

(1) Subject to regulation 42ZCK, a representative nominated under subsection 52B (3) of the Act is a Committee member for 3 years, or a shorter period stated in the person's nomination.

(2) Subject to regulation 42ZCK, a Committee member appointed under regulation 42ZCD is appointed for the term stated in the member's appointment.

(3) The term stated in an appointment must not be greater than 3 years.

(4) However, a Committee member may be nominated or appointed for further terms of up to 3 years each.

(5) The Chair of the Committee is appointed as Chair for the term stated in the appointment.

(6) The Chair may be reappointed for further terms.

42ZCI Resignation

A Committee member may resign by signed notice of resignation given to the Minister.

42ZCJ Disclosure of interests

(1) A Committee member who is aware that he or she has a direct or indirect pecuniary interest 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.

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

(a) be present during any deliberation of the Committee about the matter; or

(b) take part in any decision of the Committee about that matter.

(3) When the Committee is making a determination under subregulation (2) about a member who has made a disclosure, the member, and any other member who has a direct or indirect pecuniary interest in the matter to which the disclosure relates, must not:

(a) be present during any deliberation of the Committee; or

(b) take part in making the determination.

42ZCK Termination of Committee membership

(1) The Minister may terminate the membership of a Committee member (including a jurisdictional member) on the grounds of:

(a) physical or mental incapacity; or

(b) misbehaviour; or

(c) incompetence; or

(d) inefficiency; or

(e) failing to comply, either recklessly or intentionally, with regulation 42ZCJ.

(2) The Minister must terminate the membership of a member (including a jurisdictional member) if the member:

(a) is convicted of an offence punishable by imprisonment for 1 year or longer; or

(b) is absent without leave of absence from 3 consecutive meetings of the Committee.

42ZCL Leave of absence

(1) The Minister may grant leave of absence to the Chair of the Committee.

(2) The Chair may grant leave of absence to another Committee member.

(3) If the Chair grants leave of absence to another Committee member, the Chair may allow another person to replace the absent member for no more than 2 consecutive meetings.

(4) A replacement must have qualifications, experience and, if appropriate, expertise similar to the absent member.

Subdivision 4 Committee procedures

42ZCM Committee procedures

For subsection 52B (2) of the Act, this Subdivision sets out the procedures that the Committee must follow in holding meetings.

42ZCN Committee procedures generally

In performing its functions, the Committee:

(a) must act according to these Regulations; and

(b) must act with as little formality and as quickly as the requirements of these Regulations, and a proper consideration of the issues before the Committee, allow; and

(c) is not bound by rules of evidence; and

(d) may obtain information about an issue in any way it considers appropriate.

42ZCO Meetings

(1) The Chair of the Committee may, by written notice to the Committee, direct the Committee to hold meetings at the times and places, and to deal with matters in the manner, stated in the notice.

(2) If the Chair of the Committee considers it appropriate and efficient in the circumstances, the Committee may be directed to meet by videoconference or teleconference or to meet out of session.

(3) For this regulation:

out of session, in relation to a meeting, means a meeting in which the members take part by correspondence, electronic mail, telephone or in any other way that does not involve formal simultaneous meeting and voting.

(4) Subject to these Regulations, the procedure of a Committee's meeting is as decided by the Committee.

42ZCP Presiding member

(1) The Chair of the Committee must:

(a) preside at a Committee meeting; or

(b) nominate, in writing, a member of the Committee to preside at the meeting.

(2) If the Chair is temporarily absent from a meeting, the members present must choose a jurisdictional member to preside.

42ZCQ Quorum

(1) At a Committee meeting, a quorum exists if 11 members (including 5 jurisdictional members) are present.

(2) For this regulation, only one of the persons appointed as a representative under paragraph 42ZCD (4) (c) or (d) can be counted as a jurisdictional member.

42ZCR Voting

(1) A decision of the Committee is made by a majority of the members present and voting for the decision at a Committee meeting.

(2) However, a decision has no effect unless the majority includes a majority of the jurisdictional members present and voting.

(3) If both of the persons appointed as a representative under paragraph 42ZCD (4) (c) or (d) are present at a Committee meeting, only one of them may vote on a decision as the jurisdictional member.

(4) If it is necessary to determine which of the persons mentioned in subregulation (3) may vote as the jurisdictional member, that person is:

(a) for an issue about the regulation of medicines for human use — the person appointed under paragraph 42ZCD (4) (c); or

(b) in any other case — the person appointed under paragraph 42ZCD (4) (d).

(5) The member presiding at a Committee meeting has a deliberative vote and also has a casting vote:

(a) in the event of an equality of votes of all members present; and

(b) in the event of an equality of votes of jurisdictional members present.

42ZCS Records and reports

(1) The Committee must keep a record of its proceedings.

(2) The Committee must prepare any other report about its activities that is requested by the Minister or the Secretary.

Note Regulation 42ZCX is about records of scheduling decisions.

Subdivision 5 Scheduling procedures

42ZCT Definitions for Subdivision 5

In this Subdivision:

public submission means a submission to the Committee by a person who is not a member of the Committee.

scheduling meeting means a Committee meeting for the scheduling of a substance.

Note For ***current Poisons Standard***, ***scheduling*** and ***substance***, see s 52A of the Act.

42ZCU Public notice of scheduling meetings

(1) Before a scheduling meeting, the Chair of the Committee must publish a notice in the *Gazette*:

(a) mentioning the date of the proposed scheduling meeting; and

(b) mentioning each substance to be considered for scheduling at the meeting; and

(c) inviting public submissions to be made by a date mentioned in the notice as the closing date for public submissions (the ***closing date***).

(2) The closing date must be at least 4 weeks after publication of the *Gazette* notice.

(3) The date of the meeting must be at least a week after the closing date.

42ZCV Consideration of public submissions

(1) The Committee, in making a decision in relation to the classification and scheduling of a substance, must consider all public submissions made by the closing date that address a matter mentioned in section 52E of the Act.

(2) The Committee need not consider a public submission made after the closing date.

42ZCW Other matters to be considered by Committee

(1) A submission prepared in relation to a substance by a Committee member and submitted before or at the meeting about the scheduling of the substance must be considered by the Committee at the meeting.

(2) The Committee must also take into account any recommendation of a subcommittee about the substance.

42ZCX Record of reasons for scheduling decisions

The Committee must make a record of the reasons for a scheduling decision.

Note Regulation 42ZCS provides that the Committee must keep a record of its proceedings.

42ZCY Public notice of amendment

(1) A notice under subsection 52D (4) of the Act must include:

(a) an indication of the amendment; and

(b) instruction on how the record of the reasons for the amendment may be accessed; and

(c) an invitation to persons who made a public submission in relation to the substance the subject of the amendment to make a further submission.

(2) An amendment must not be expressed to come into force earlier than 4 weeks after publication of the notice.

(3) Nothing in subregulation (1) requires the Committee to disclose in the notice, or to provide access to, information that it properly regards as requiring confidentiality for commercial reasons.

42ZCZ Further public submissions

(1) A submission in response to an invitation mentioned in paragraph 42ZCY (1) (c) must be made within 2 weeks after publication of the notice making the invitation.

(2) The submission must:

(a) address a matter mentioned in section 52E of the Act; and

(b) be relevant to the reasons recorded for making the amendment.

(3) If a submission is made to the Committee under this regulation, the Committee must consider the submission and then:

(a) confirm the amendment; or

(b) vary the amendment; or

(c) set aside the amendment, replace it with a new scheduling decision and publish notice of the decision under section 52D of the Act.

42ZCZA Public consultation by subcommittee

(1) The Committee may assign its public consultation responsibilities and functions under this Subdivision to a subcommittee.

(2) The subcommittee must give the Committee a written report setting out the manner of its compliance with those responsibilities and functions.

Note Regulation 42ZCB deals with subcommittees.

42ZCZB Urgent scheduling

(1) This regulation applies if the Chair of the Committee considers that, in the interests of public health and safety, urgent scheduling of a substance is necessary.

(2) If it is not practicable to follow the procedures for public consultation prescribed by this Subdivision before scheduling, the Committee may make a scheduling decision without following the procedures.

(3) A scheduling decision made without following the procedures must be reviewed by the Committee as soon as practicable.

(4) The procedures for public consultation prescribed by this Subdivision apply to the review as if the review were a scheduling meeting.

Division 4 Complementary Medicines Evaluation Committee

Subdivision 1 Interpretation

42ZD Definition

In this Division:

Committee means the Complementary Medicines Evaluation Committee.

Note The Complementary Medicines Evaluation Committee is established by section 52G of the Act.

Subdivision 2 Functions of Committee

42ZE Committee's evaluating function

(1) The Committee may evaluate, and report to the Minister or Secretary about any of the following:

(a) a complementary medicine;

(b) an ingredient in a complementary medicine;

(c) a kind of ingredient in a complementary medicine;

(d) therapeutic goods referred to the Committee, by the Minister or the Secretary, for this regulation.

(2) The matters to be included in a report include a recommendation about the following, as applicable:

(a) whether or not a complementary medicine should remain in the Register;

(b) whether or not a complementary medicine should be included in the Register;

(c) whether or not an ingredient or kind of ingredient should be included in Schedule 14, or mentioned in Schedule 4 as the therapeutically active ingredient in a preparation mentioned in item 3 of Part 1 of that Schedule.

42ZF Committee may give advice to Minister or Secretary

(1) The Committee may, in relation to a thing mentioned in subregulation 42ZE (1), give the Minister or Secretary scientific and policy advice about the following matters, as applicable:

(a) the import or export of the complementary medicine, ingredient, kind of ingredient or kind of therapeutic goods;

(b) registration or listing of the complementary medicine, ingredient, kind of ingredient or kind of therapeutic goods;

(c) the manufacture, supply and use of the complementary medicine, ingredient, kind of ingredient or kind of therapeutic goods.

Note For the definition of ***supply***, see subsection 3 (1) of the Act.

(2) An advice given about a thing mentioned in subregulation (1) may include, as applicable:

(a) the Committee's opinion about its safety; and

(b) an assessment of short-term and long-term risks and claimed benefits of its use; and

(c) the Committee's opinion about its quality; and

(d) the Committee's opinion about its efficacy; and

(e) if the advice is about therapeutic goods — the Committee's opinion about the indications of therapeutic goods; and

(f) if the advice is about therapeutic goods in relation to which a claim has been made to which subsection 28 (6) of the Act applies:

(i) the Committee's opinion about the claim; and

(ii) the Committee's opinion about the amount, standard or type of information or evidence used to support a claim.

Note For the definition of ***indications***, see subsection 3 (1) of the Act.

42ZG Committee may establish sub-committees

(1) The Committee may appoint sub-committees, consisting of members of the Committee and other persons.

(2) The function of a sub-committee is to inquire into, and report to the Committee on, any specified matter that is within the functions of the Committee.

42ZH Minister or Secretary may seek further advice

(1) If the Committee gives advice, under this Division, to the Minister or the Secretary, the Minister or the Secretary may give a copy of that advice to another Committee established under Division 1 of this Part.

(2) A Committee to which a copy of an advice is given may make comments to the Minister or the Secretary about that advice.

42ZI Committee may seek advice and assistance

The Committee may, in performing its functions under this Division, seek advice from other persons.

Subdivision 3 Constitution of Committee

42ZJ Establishment and membership of Committee

The Complementary Medicines Evaluation Committee established under subsection 52G (1) of the Act is constituted in accordance with this Subdivision.

42ZK Appointment of Committee members

(1) The Minister must appoint members of the Committee in accordance with this regulation.

(2) An appointment of a member must be in writing.

(3) The Committee must include at least 8, but no more than 12, members.

42ZL Expertise and experience of members

(1) In appointing members, the Minister must take into account candidates' expertise and experience in the following fields:

(a) complementary medicine practice;

(b) consumer representation;
(c) general medical practice;
(d) herbal medicine;
(e) naturopathy;
(f) nutrition or nutritional medicine;
(g) pharmacognosy;
(h) pharmacology;
(i) governmental regulation;
(j) toxicology.

(2) At least 4 members of the Committee must have professional clinical experience in a field mentioned in subregulation (1).

42ZM Appointment of Chair

The Minister must, in writing, appoint a member of the Committee to be its Chair.

42ZN Minister may nominate expert advisers

(1) The Minister may nominate a person to give expert advice to the Committee to assist it in the performance of its functions.

(2) If the Minister nominates a person for this regulation, the Committee may ask that person for advice about performing a function of the Committee.

(3) No more than 8 persons may be nominated under this regulation.

(4) Regulations 42ZO, 42ZP, 42ZQ and 42ZR apply to a person nominated under this regulation as if he or she were a member of the Committee.

Example

In nominating a person for this regulation, the Minister may consider the person's expertise and experience in any of the following areas:

(a) traditional Chinese medicine;
(b) homoeopathy;
(c) Ayurvedic medicine;
(d) aromatherapy;

(e) regulatory affairs, in particular, scheduling of medicines;

(f) formulating, designing or manufacturing complementary medicines;

(g) consumer representation.

42ZO Term of appointment

(1) A Committee member is appointed for the term stated in the member's appointment.

(2) The term stated in the appointment must not be greater than 3 years.

(3) However, a Committee member may be reappointed for further terms of up to 3 years each.

(4) The Chair of the Committee is appointed as Chair for the term stated in the Chair's appointment.

(5) The Chair may be reappointed for further terms.

42ZP Resignation

A Committee member may resign by signed notice of resignation given to the Minister.

42ZQ Disclosure of interests

(1) A Committee member who is aware that he or she has a direct or indirect pecuniary interest 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.

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

(a) be present during any deliberation of the Committee about the matter; or

(b) take part in any decision of the Committee about that matter.

(3) When the Committee is making a determination under subregulation (2) about a member who has made a disclosure, the member, and any other member who has a direct or indirect pecuniary interest in the matter to which the disclosure relates, must not:

(a) be present during any deliberation of the Committee; or

(b) take part in making the determination.

(4) A member of a sub-committee under regulation 42ZG, who is aware that he or she has a direct or indirect pecuniary interest in a matter being considered, or about to be considered, at a meeting of the sub-committee must, without delay, disclose the nature of the interest at, or before, the meeting of the sub-committee.

42ZR Termination of appointment

(1) The Minister may terminate a Committee member's appointment on the grounds of:

(a) physical or mental incapacity; or

(b) misbehaviour; or

(c) incompetence; or

(d) inefficiency; or

(e) failing to comply, either recklessly or intentionally, with regulation 42ZQ.

(2) The Minister must terminate the member's appointment if the member:

(a) is convicted of an offence punishable by imprisonment for 1 year or longer; or

(b) is absent without leave of absence from 3 consecutive meetings of the Committee.

42ZS Leave of absence

(1) The Minister may grant leave of absence to the Chair of the Committee.

(2) The Chair may grant leave of absence to another Committee member.

Subdivision 4 Committee procedures

42ZT Committee procedures

For subsection 52G (3) of the Act, this Subdivision sets out the procedures that the Committee must follow in holding meetings.

42ZU Committee procedures generally

(1) In performing its functions, the Committee:

(a) must act according to these Regulations; and

(b) must act with as little formality and as quickly as the requirements of these Regulations, and a proper consideration of the issues before the Committee, allow; and

(c) is not bound by rules of evidence; and

(d) may obtain information about an issue in any way it considers appropriate; and

(e) may receive information or submissions orally or in writing.

(2) In addition, the Committee 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.

42ZV Meetings

(1) The Chair of the Committee may, by written notice to the Committee, direct the Committee to hold meetings at the times and places, and to deal with matters in the manner, stated in the notice.

(2) Subject to these Regulations, the procedure of a Committee's meeting is as decided by the Committee.

42ZW Presiding member

(1) The Chair of the Committee must:

(a) preside at a Committee meeting; or

(b) 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.

42ZX Quorum

At a Committee meeting, a quorum exists when at least half of the members are present.

42ZY 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, in the event of an equality of votes, also has a casting vote.

42ZZ Records and reports

(1) The Committee must keep a record of its proceedings.

(2) The Committee must prepare any other report about its activities that is requested by the Minister or the Secretary.

Division 5 Medicines Evaluation Committee

Subdivision 1 Interpretation

42ZZA Definitions

In this Division:

Committee means the Medicines Evaluation Committee established by subregulation 42ZZB (1).

consultant physician has the meaning given in section 3 of the *Health Insurance Act 1973*.

medical practitioner has the meaning given in section 3 of the *Health Insurance Act 1973*.

Subdivision 2 Establishment of Committee

42ZZB Establishment and constitution of Committee

(1) A committee called the Medicines Evaluation Committee is established.

(2) The Committee has the functions mentioned in Subdivision 3 of this Division.

(3) The Committee must be constituted in accordance with Subdivision 4 of this Division.

(4) The Committee must hold meetings, and make decisions, in accordance with Subdivision 5 of this Division.

Subdivision 3 Functions of Committee

42ZZC Committee's evaluating function

(1) The Committee may evaluate, and report to the Minister or Secretary about, any of the following:

(a) an OTC medicine;

(b) an ingredient in an OTC medicine;

(c) a kind of ingredient in an OTC medicine;

(d) therapeutic goods identified by the Committee;

(e) therapeutic goods referred to the Committee, by the Minister or the Secretary, for this regulation.

Example

Examples of OTC medicines that the Committee may evaluate, and report about, include:

- OTC medicines that are included in the Register
- OTC medicines for which an application for inclusion in the Register has been made.

(2) The matters to be included in a report for subregulation (1) include, if appropriate, a recommendation about whether or not a particular kind of therapeutic goods should be included in the part of the Register for listed goods.

42ZZD Committee may give advice to Minister or Secretary

(1) The Committee may, in relation to a thing mentioned in subregulation 42ZZC (1), give to the Minister or Secretary scientific and policy advice about the following matters, as applicable:

(a) the import or export of the OTC medicine, ingredient, kind of ingredient or kind of therapeutic goods;

(b) registration or listing of the OTC medicine, ingredient, kind of ingredient or kind of therapeutic goods;

(c) the manufacture, supply and use of the OTC medicine, ingredient, kind of ingredient or kind of therapeutic goods.

Note For the definition of ***supply***, see subsection 3 (1) of the Act.

(2) An advice given about a thing mentioned in subregulation (1) may include, as applicable:

(a) the Committee's opinion about its safety; and

(b) an assessment of short-term and long-term risks and claimed benefits of its use; and

(c) the Committee's opinion about its quality; and

(d) the Committee's opinion about its efficacy; and

(e) if the advice is about therapeutic goods — the Committee's opinion about the indications of the therapeutic goods; and

(f) if the advice is about therapeutic goods in relation to which a claim has been made to which subsection 28 (6) of the Act applies:

(i) the Committee's opinion about the claim; and

(ii) the Committee's opinion about the amount, standard or type of information or evidence used to support a claim.

Note For the definition of ***indications***, see subsection 3 (1) of the Act.

42ZZE Committee may establish sub-committees

(1) The Committee may appoint sub-committees, consisting of members of the Committee and other persons.

(2) The function of a sub-committee is to inquire into, and report to the Committee on, any matter that is within the functions of the Committee.

42ZZF Minister or Secretary may seek further advice

(1) If the Committee gives advice, under this Division, to the Minister or the Secretary, the Minister or the Secretary may give a copy of that advice to another committee established under the Act.

(2) A Committee to which a copy of an advice is given may make comments to the Minister or the Secretary about that advice.

Example

Examples of Committees to which the Minister or Secretary may give a copy of advice include:

- the Complementary Medicines Evaluation Committee
- the National Drugs and Poisons Schedule Committee
- a committee established under Division 1 of this Part.

42ZZG Committee may seek advice and assistance

The Committee may, in performing its functions under this Division, seek advice from other persons.

Subdivision 4 Constitution of Committee

42ZZH Establishment and membership of Committee

The Committee is constituted in accordance with this Subdivision.

42ZZI Appointment of Committee members

(1) The Minister must appoint members of the Committee in accordance with this regulation.

(2) An appointment of a member must be in writing.

(3) The Committee must include at least 8, but no more than 12, members.

42ZZJ Expertise and experience of members

In deciding whether to appoint a person to be a member of the Committee, the Minister must take into account the person's expertise and experience in the following fields:

(a) general medical practice;

(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) government regulation;

(j) consumer representation.

Example

For paragraph (b), the Minister would need to take into account candidates' expertise and experience in medical specialties, including paediatric and geriatric medicine.

42ZZK Appointment of Chair

The Minister must, in writing, appoint a member of the Committee to be its Chair.

42ZZL Minister may nominate expert advisers

(1) The Minister may nominate a person to give expert advice to the Committee to assist it in the performance of its functions.

(2) If the Minister nominates a person under subregulation (1), the Committee may ask that person for advice about performing a function of the Committee.

(3) The Committee may have no more than 8 such advisers.

(4) Regulations 42ZZM, 42ZZN, 42ZZO and 42ZZP apply to a person nominated under this regulation as if he or she were a member of the Committee.

42ZZM Term of appointment

(1) A Committee member is appointed for the term stated in the appointment.

(2) The term stated in an appointment must not be greater than 3 years.

(3) However, a Committee member may be reappointed for further terms of up to 3 years each.

(4) The Chair of the Committee is appointed as Chair for the term stated in the Chair's appointment.

(5) The Chair may be reappointed for further terms while he or she is a member of the Committee.

42ZZN Resignation

A Committee member may resign by signed notice of resignation given to the Minister.

42ZZO Disclosure of interests

(1) A Committee member who is aware that he or she has a direct or indirect pecuniary interest 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.

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

(a) be present during any deliberation of the Committee about the matter; or

(b) take part in any decision of the Committee about that matter.

(3) When the Committee is making a determination under subregulation (2) about a member who has made a disclosure, the member, and any other member who has a direct or indirect pecuniary interest in the matter to which the disclosure relates, must not:

(a) be present during any deliberation of the Committee; or

(b) take part in making the determination.

(4) A member of a sub-committee under regulation 42ZZE, who is aware that he or she has a direct or indirect pecuniary interest in a matter being considered, or about to be considered, at a meeting of the sub-committee must, without delay, disclose the nature of the interest at, or before, the meeting of the sub-committee.

42ZZP Termination of appointment

(1) The Minister may terminate a Committee member's appointment on the grounds of:

(a) physical or mental incapacity; or

(b) misbehaviour; or

(c) incompetence; or

(d) inefficiency; or

(e) failing to comply, either recklessly or intentionally, with regulation 42ZZO.

(2) The Minister must terminate the member's appointment if the member:

(a) is convicted of an offence punishable by imprisonment for 1 year or longer; or

(b) is absent without leave of absence from 3 consecutive meetings of the Committee.

42ZZQ Leave of absence

(1) The Minister may grant leave of absence to the Chair of the Committee.

(2) The Chair may grant leave of absence to another Committee member.

Subdivision 5 Committee procedures

42ZZR Committee procedures

This Subdivision sets out the procedures that the Committee must follow in holding meetings.

42ZZS Committee procedures generally

(1) In performing its functions, the Committee:

(a) must act according to these Regulations; and

(b) must act with as little formality and as quickly as the requirements of these Regulations, and a proper consideration of the issues before the Committee, allow; and

(c) is not bound by rules of evidence; and

(d) may obtain information about an issue in any way that it considers appropriate; and

(e) may receive information or submissions orally or in writing.

(2) In addition, the Committee 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.

42ZZT Meetings

(1) The Chair of the Committee may, by written notice to the Committee, direct the Committee to hold meetings at the times and places, and to deal with matters in the manner, stated in the notice.

(2) Subject to these Regulations, the procedure of a Committee's meeting is as decided by the Committee.

42ZZU Presiding member

(1) The Chair of the Committee must:

(a) preside at a Committee meeting; or

(b) nominate, in writing, 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.

42ZZV Quorum

At a Committee meeting, a quorum exists when at least half of the members are present.

42ZZW 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, in the event of an equality of votes, also has a casting vote.

42ZZX Records and reports

(1) The Committee must keep a record of its proceedings.

(2) The Committee must prepare any other report about its activities that is requested by the Minister or the Secretary.

Part 7 Fees, costs and charges

43 Fees

(1) Subject to the other provisions of this Part, the fee specified in column 3 of an item in Part 2 of Schedule 9 is prescribed for the matter that, in relation to that fee, is specified 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.

43AA Fee for evaluation — reduction in certain circumstances

(1) The fee payable under Schedule 9 for an application to which regulation 16D applies is reduced by 25% if the Secretary does not notify the applicant of the decision on the application within the period specified in subregulation 16D (3) that applies to the application.

(2) In the case of an application mentioned in subregulation (1):

(a) the amount payable on lodgment of the application is the amount of the fee reduced by 25%; and

(b) if the reduction mentioned in that subregulation does not apply, the remainder of the fee is payable on the notification of the decision on the application.

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 Schedule 9 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 Schedule 9 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;

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 $7 240;

(b) for an application involving the evaluation of:

(i) manufacture; or

(ii) quality control; or

(iii) sterile manufacture; or

(iv) testing information;

is $6 040;

(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 $6 040; and

(ca) in the case of an application involving the evaluation of software — is reduced to $6 040;

(d) for an application involving the evaluation of human clinical information — is $24 200;

(e) for an application involving the evaluation of a confirmatory review of clinical information — is $6 040; and

(f) for an application involving confirmatory evaluation of overseas reports or data lodged to support the application — is $6 040.

(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 $3 630; 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 $3 630; 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 $3 630; and

(ca) in the case of an application involving the evaluation of software — is reduced to $3 630; and

(d) in the case of an application involving the evaluation of human clinical information — is reduced to $3 630; and

(e) in the case of an application involving confirmatory evaluation of overseas reports or data lodged to support the application — is reduced to $3 630.

(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 $1 330; 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 $1 330; 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 $1 330; and

(ca) in the case of an application involving the evaluation of software — is reduced to $1 330; and

(d) in the case of an application involving review of human clinical information — is reduced to $1 330; and

(e) in the case of an application involving confirmatory evaluation of overseas reports or data lodged to support the application — is reduced to $1 330.

(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 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 Charges reduced if annual turnover is not more than $65 000

(1) Subject to subregulation (2), if the wholesale turnover of therapeutic goods of a person who is required to hold a licence under Part 3-3 of the Act is not more than $65 000 in a financial year, the annual charge payable by the person for a licence that is in force at any time during that financial year is half of the amount otherwise payable under subregulation 3 (2) of the *Therapeutic Goods (Charges) Regulations 1990* in respect of that licence.

(2) Subregulation (1) does not apply in relation to the annual charge payable in respect of a licence that is in force for the manufacture of human blood and blood components.

Part 8 Miscellaneous

46A Delegation under the Act

The appointment of National Manager, Therapeutic Goods Administration is declared for the purposes of paragraph 57 (1) (c) of the Act to be an appointment the holder of which may be a delegate of the Minister or the Secretary under section 57 of the Act.

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 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, medical devices that contain medicines, or medical devices that incorporate, or are intended to incorporate, as an integral part, a medicine 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.

(3) For the purposes of subsection 61 (6) of the Act, the Secretary may release therapeutic goods information of a kind that relates to the evaluation of therapeutic goods by the Australian Drug Evaluation Committee by publishing the information in the *Gazette*.

(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.

(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 paragraph 19 (1) (a) of the Act

(1) In this regulation, ***delegation*** means a delegation, under subsection 57 (3) of the Act, of powers of the Secretary under paragraph 19 (1) (a) of the Act, that relates to specified therapeutic goods.

(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 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;

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 item of therapeutic goods to which the approval relates has an illness or condition that requires treatment with the item; and

(b) an ethics committee has agreed to the granting of approval under paragraph 19 (1) (a) of the Act for the use, in the circumstances in which the delegate grants the approval, of the item of therapeutic goods to which the delegation relates.

47B Provision of information concerning medicines 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) or 41HC (1) of the Act to supply a medicine 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 item of therapeutic goods (including medical devices) 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 and medical devices that the person gave during that period.

(4) A report by a person mentioned in paragraph (1) (b) must list each item of therapeutic goods (including medical devices) 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 or 41HA of the Act applies; and

(ii) to which paragraph 19 (1) (a) or 41HB (1) (d) of the Act applies; and

(iii) to which paragraph 19 (1) (b) or 41HB (1) (e) of the Act applies; and

(iv) to which subsection 19 (5) 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);

(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.

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

(subregulation 4 (2))

Column 1 Item No.	Column 2 Body
1	Acupuncture Association of Australia
2	Acupuncture Ethics and Standards Organisation
2A	Association of Natural Health Practitioners Limited
3	Association of Traditional Health Practitioners Incorporated
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

Column 1 Item No.	Column 2 Body
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	The Australian Association of Homotoxicology Incorporated
26B	The Australian Podiatry Association (NSW)
26BA	The Homeopathic Medicine Association Inc.
27	The New South Wales Research Association of Traditional Chinese Medicine

Schedule 2 Prohibited and required representations

(regulation 6B)

Part 1 Prohibited representations

Column 1 Item No.	Column 2 Representation	Column 3 Therapeutic goods
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 (b) are, or contain, a substance described as a vitamin otherwise than by a description specified in Column 2 or 3 of Part 3 of this Schedule	all therapeutic goods
4	a representation referred to in paragraph 7.1.3 (a) or (b) of the Therapeutic Goods Advertising Code	analgesics

Column 1 Item No.	Column 2 Representation	Column 3 Therapeutic goods
5	a representation containing a reference to bacteriostatic activity, except where it is made in conjunction with a reference to bactericidal activity	disinfectants
6	a representation: (a) containing reference to the Rideal-Walker test or the Phenol Coefficient; or (b) on any label, containing a reference to the results of laboratory tests on micro-organisms, other than a representation provided by leaflet or on a label enclosed with the goods in their package; or (c) containing a reference to the achievement of sterility except where the representation is approved in writing by the Secretary; or (d) contradicting or conflicting with the common name; or (e) that is not more specific than the common name as a description or measure of activity against micro organisms; or (f) containing a reference to an effect against viruses, except a representation that is approved in writing by the Secretary; or (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	disinfectants and antiseptics

Column 1 Item No.	Column 2 Representation	Column 3 Therapeutic goods
	(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 (b) expresses the quantity of a vitamin or a mineral contained in a preparation as a percentage or proportion of the recommended daily or dietary intake or allowance	vitamins and minerals

Part 2 Required representations

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

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

Column 1 Item	Column 2 Substance	Column 3 Name
1	Vitamin A	—
2	Thiamine	Vitamin B1
3	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: (a) implantable intra-ocular lenses, other than lenses that are included in item 13 or 14 of Part 1 of Schedule 4; or (b) intra-uterine contraceptive devices; or (c) implantable cardiac pacing systems, including pulse generators, defibrillators, cardioverters, antitachycardia devices and their implantable accessories; or

Item No.	Therapeutic goods
	(d) prosthetic heart valves; or (e) intra-ocular visco-elastic fluids; or (f) powered medicine infusion systems and accessories that regulate the flow of infusate, other than: (i) on-implantable powered medicine infusion systems where the only regulation of flow that is achieved is done by driving a pressurised fluid through a thin calibrated bore restricter that does not allow for any adjustment to be made to the flow rate; or (ii) accessories to systems referred to in subparagraph (i); or (g) devices of human, animal, bacterial or recombinant origin for use in or on the body of a person, other than devices for that use that: (i) are manufactured using animal-derived waxes; or (iv) incorporate heparin, unless heparin is being delivered as a medicine; or (v) are sutures conforming to a standard determined under Part 3-1 of the Act; or (vi) are made from sintered hydroxyapatite; or (vii) incorporate gelatine that conforms to generally accepted pharmacopoeial standards; or (h) implantable breast prostheses consisting of, or containing, material of fluid consistency that is not only: (i) water; or (ii) a saline solution; if unintentional migration of that material to a part of the body away from the site of implantation could occur.
4	active implantable therapeutic devices, other than: (a) auditory nerve stimulators; or (b) bone growth stimulators; or (c) incontinence control stimulators; or (d) peripheral nerve stimulators; or (e) spinal cord stimulators; that were being supplied on 3 July 1995

Item No.	Therapeutic goods
5	implantable therapeutic devices that: (a) incorporate an ancillary medicinal substance; or (b) are designed to incorporate an ancillary medicinal substance; if the purpose of the incorporation is to enhance the function of the device

Part 2 Therapeutic devices attracting a lower fee

Item No.	Therapeutic goods
2	therapeutic devices, to which a standard determined under subsection 10 (1) of the Act applies, that are bedside or ambulatory infusion pumps, other than pumps where the only regulation of flow that is achieved is done by driving a pressurised fluid through a thin calibrated bore restricter that does not allow for any adjustment to be made to the flow rate
3	implantable breast prostheses, except: (a) those referred to in Part 1; and (b) tissue expanders that are: (i) filled only with water or a saline solution; and (ii) not intended by the manufacturer to be left permanently in place
4	devices that are barriers indicated for contraception or for prevention of the transmission of disease in the course of penile penetration during sexual intercourse, other than rubber diaphragms and condoms that conform to a standard under Part 3-1 of the Act
5	instrument grade disinfectants and sterilants claimed to be fungicides, sporicides, tuberculocides or virucides, that are intended by the manufacturer to be used on: (a) a critical medical device; or (b) a semi critical medical device
6	hospital grade or household grade disinfectants that are claimed to be sterilants, fungicides, sporicides, tuberculocides or virucides

Item No.	Therapeutic goods
7	diagnostic goods for *in vitro* use that are: (a) goods for use in the diagnosis of Human Immunodeficiency Virus; or (b) goods for use in the diagnosis of hepatitis C virus
8	control material for use with diagnostic goods for *in vitro* use

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, 4 or 5 of Part 1 of Schedule 3 applies; or (aa) Part 2 of Schedule 3 applies; or (b) item 1, 2, 3, 4, 5, 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; 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

Item No.	Therapeutic goods
	(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 subject to a Schedule to 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

Item No.	Therapeutic goods
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 2604:1998, 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;

Item No.	Therapeutic goods
	(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; 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 (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

Item No.	Therapeutic goods
	(c) the goods are included in a Schedule to 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 solely of medicines if Part 3-2 of the Act applies to any of the individual therapeutic goods contained in the kit
13	intraocular lenses that are: (a) made of poly(methyl methacrylate); and (b) designed for placement in the posterior chamber of the eye; and (c) monofocal; and (d) included in the Register: (i) after being evaluated under section 25 of the Act for registration; or (ii) in accordance with subsection 66 (3) of the Act; and
14	intraocular lenses that: (a) are derived from a lens of a kind referred to in item 13; and (b) do not differ from the lens from which they are derived except to the extent permitted by guidelines approved by the Secretary
15	non-powered endoscopes and endoscopic accessories
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

Approved Name	Synonym
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

Name
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

Name
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

Name
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)

Name
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

Item	Plant material	Qualification
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

Item	Plant material	Qualification
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

Item	Plant material	Qualification
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)

Item	Plant material	Qualification
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

Item	Plant material	Qualification
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

Item	Plant material	Qualification
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

Item	Plant material	Qualification
		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;

Item	Plant material	Qualification
		(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

Item	Plant material	Qualification
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

Item	Plant material	Qualification
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

Item	Plant material	Qualification
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 leaf

Bacterial 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

Item	Substance	Maximum amount per dosage form	Maximum daily dose (all dosage forms)
1C	Boric acid		3 mg of boron
1	Chromium nicotinate		50 µg of chromium
2	Chromium picolinate		50 µg of chromium
3	High chromium yeast		50 µg of chromium
4	Cupric citrate		750 µg of copper
4A	Molybdenum trioxide		125 µg of molybdenum
5	High molybdenum yeast		62.5 µg 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 Part 3-2 of the Act

(subregulation 12 (1))

Column 1 Item No.	Column 2 Therapeutic goods
1	therapeutic goods that are imported for use in the treatment of the importer or the importer's immediate family where: (a) the goods do not contain a substance the importation of which is prohibited under the *Customs Act 1901*; and (b) in the case of 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 (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

Column 1 Item No.	Column 2 Therapeutic goods
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
5	custom-made therapeutic devices that are produced for a particular person for therapeutic application to that person, other than the following goods: (a) therapeutic devices referred to in item 3 of Part 1 of Schedule 3; (b) therapeutic devices referred to in an item in Part 2 of Schedule 3; (c) electronic devices that must be programmed for each patient using those devices
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	the following therapeutic devices and parts of therapeutic devices: (a) components and parts of therapeutic devices intended for use in the manufacture, installation, repair or maintenance of devices that are not provided separately to the consumer as an accessory or consumable component, other than: (i) components for artificial limbs;or

Column 1 Item No.	Column 2 Therapeutic goods

(ii) programmers for implantable electronic devices; or

(iii) components of implantable devices that are assembled in the body; or

(b) diagnostic goods for *in vitro* use other than:

(i) goods for home use; or

(ii) goods that incorporate material of human origin; or

(iii) goods supplied as a pharmaceutical benefit; or

(v) containers of a kind referred to in paragraph 7 (l); or

(c) non-implantable, non-powered diagnostic tools that:

(i) are not supplied in a sterile state; and

(ii) are not intended to monitor a physiological process; and

(iii) are not referred to in paragraph (b); or

(d) non-powered medical or dental instruments that:

(i) depend on manual dexterity for their use; and

(ii) are not supplied in whole or in part in a sterile state;

except endoscopes and endoscopic accessories, flexible tubes, catheters, cannulae, fluid and gas lines and other instruments that introduce fluids or gases to, or remove them from, the body; or

(e) manufacturing, laboratory and dispensary equipment used in diagnosis or in the preparation of therapeutic goods except:

(i) equipment specifically designed to process a patient's blood or other tissues for re-introduction to the patient; or

(ii) a bench top or portable steriliser, not permanently connected to plumbing or electrical wiring, used to sterilise medical or dental instruments; or

(f) therapeutic devices for dental use that are:

(i) constructed externally to the mouth; and

(ii) fitted or fixed into the mouth on a temporary or permanent basis; and

Column 1 Item No.	Column 2 Therapeutic goods

(iii) intended for protection, or to correct an irregularity or deficiency;

other than the following:

(v) dental restorative materials;

(vi) devices that, when used, are implanted directly into bone or soft tissue;

(vii) therapeutic devices for dental use included in an item in Schedule 3 or 4; or

(fa) therapeutic devices for dental use that are dental impression materials; or

(g) non-powered devices used in general patient care, being devices that do not constitute or contribute to a specific diagnosis, monitoring or treatment of a medical condition; or

(h) furniture other than powered appliances for use in diagnosis or treatment of a medical condition; or

(i) linen and bedding other than linen and bedding supplied in a sterile state; or

(j) protective clothing for patients or health workers, except:

(i) clothing supplied in a sterile state; or

(ii) surgeon's gloves, patient examination gloves and other protective gloves for the prevention of contact with body fluids or body tissue; or

(iii) patient nuclear radiation shields and radiation shielding apparel; or

(k) communications equipment except telemetry equipment and other patient monitoring equipment that directly monitors a physiological process; or

(l) containers other than:

(i) syringes; or

(ii) single use containers designed for the collection, storage and transfer of blood for diagnostic testing (other than single use containers recommended by the manufacturer to be used only in equipment measuring the physical properties of blood); or

Column 1 Item No.	Column 2 Therapeutic goods
	(iii) containers designed for the collection of blood for transfusion; or (iv) containers designed for the collection of blood for use in the manufacture of blood products; or (v) containers designed for the storage of blood and blood components for parenteral administration; or (vi) containers, not made of glass, designed for the storage and parenteral administration of therapeutic goods (commonly referred to as "large volume parenteral infusion bags"); or (vii) bags designed for the collection of fluids drained from the body of a patient (commonly referred to as "drainage bags"); or (m) therapeutic devices: (i) imported by their users before the commencement of the Act; and (ii) that are still in use for administration to, or application in the treatment of, patients; or (n) non-sterile, non-powered therapeutic devices that are: (i) medicine droppers, measures or spoons; or (ii) non-absorbent applicators; or (iii) absorbent applicators designed for use with inhalations; or (o) non-powered orthoses or splints that do not exert traction; or (p) non-powered hot or cold packs; or (q) human tissue for implantation in the human body that is obtained, stored and supplied without any deliberate alteration to its biological or mechanical properties by institutions the procedures of which conform with principles determined under subsection 36 (1) of the Act

Column 1 Item No.	Column 2 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;

Column 1 Item No.	Column 2 Therapeutic goods

(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 items 5 and 6 of Part 2 of Schedule 3; or

(ii) disinfectants included in item 16 of Part 1 of Schedule 4; or

(iii) disinfectants for use with contact lenses;

(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 2604:1998, 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;

Column 1 Item No.	Column 2 Therapeutic goods
9	the following medicines: (a) starting materials used in the manufacture of therapeutic goods, except when: (i) prepackaged for supply for other therapeutic purposes; or (ii) formulated as a dosage form; (b) 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 the operation of Part 3-2 of the Act subject to conditions

(subregulation 12 (1A))

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
1	Therapeutic goods imported into Australia that are held under the direct control of the sponsor, until the goods are: (a) the subject of a notification under item 3; or (b) approved for importation into Australia under subsection 19 (1) of the Act; or (c) authorised for supply under subsection 19 (5) of the Act; or (d) dispensed as a medicine 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 — the goods must be destroyed within 1 month of the end of that period; and (ii) in the case of therapeutic devices — the devices must be destroyed or returned to the consignor of the devices within 1 month of the end of that period; and

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
		(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 or 26 of the Act in relation to the goods	(a) the sponsor must: (i) keep records relating to 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 of the Act in relation to the goods before their importation; and (b) if the goods are not registered or listed: (i) the goods must be destroyed; or

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
		(ii) in the case of therapeutic devices — the devices must be destroyed or returned to the consignor of the devices within 1 month of the decision not to register or list the devices
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; 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

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
		(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

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
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

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
		(ii) for each of the goods that is not a therapeutic device — 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, 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

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
	(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) 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	(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
7	Therapeutic goods, or parts of therapeutic goods, that form part of one of the following device kits: (a) orthopaedic fixation systems; (b) diagnostic goods for *in vitro* use that are reagents, reagent products or a combination of those products;	(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

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
	(c) medicine delivery systems in which the medicine is supplied in a device that acts as a container; (d) dental restorative systems	(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

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
		(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 — 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 directed by the Secretary, under clause 7 of Schedule 5B, to be exported	the provisions of Schedule 5B continue to apply to the goods, as if the goods were not exempt from the operation of section 30G of the Act

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
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

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
		(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 — 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.

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
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

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
		(g) the person mentioned in paragraph (f) must: (i) carry a list, in English, of the quantity and nature of the therapeutic goods imported; and (ii) for each of the goods that is not a therapeutic device — 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

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
		(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 — include in the list the generic name and strength of the active ingredient of the goods; and

Column 1 Item	Column 2 Therapeutic goods	Column 3 Conditions
		(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

(regulation 12AAB)

1 Early cessation of exemption — notice of goods held

(1) A person who is given notice under subregulation 12AAA (2) must 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.

(2) Subclause (1) must be complied with:

(a) if the notice under subregulation 12AAA (2) is given before the exemption ceases to have effect for the goods — within 7 days after the exemption so 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.

3 Storage and disposal of unused emergency goods

(1) A person who has control over unused emergency goods must ensure that those goods are stored in a way that ensures that:

(a) the goods are only accessible for supply, export, use or disposal in accordance with the Act and these Regulations; and

(b) the security of the goods is appropriate to the level of risk that the goods could pose to the public and the environment; and

(c) the integrity of the condition of the goods is maintained.

(2) A person may dispose of unused emergency goods only in accordance with a direction given by the Secretary under subclause 4 (1).

4 Direction for disposal of unused emergency goods

(1) The Secretary may direct, in writing, any person who has control over unused emergency goods to dispose of the goods 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

If storage of particular unused emergency goods at a particular location poses, or would pose, a risk to the public or the environment, the Secretary may direct that the goods be stored at a specified location that will ensure compliance with subclause 3 (1).

6 Disposal of unused emergency goods — destruction

(1) The Secretary may direct that unused emergency goods be destroyed within the time specified in the direction if any of the following applies:

(a) the goods have passed their expiry date;

(b) the goods no longer conform to a standard that applies to the goods;

(c) use of the goods poses, or would pose, a risk to public health;

(d) storage of the goods at their current location and any other location poses, or would pose, a risk to the public or the environment;

(e) 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;

(f) the person who has control over the goods requests that the goods be destroyed.

(2) A person directed to destroy the goods may destroy the goods 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 — export

(1) This clause applies to unused emergency goods to which any of paragraphs 6 (1) (a) to (e) applies.

(2) The Secretary may direct that the goods be exported to a country, instead of directing that they be destroyed, if a relevant authority of the country has confirmed its willingness to accept the goods.

(3) A person directed to export the goods must ensure that, during exportation:

(a) the goods are only accessible for purposes relating to the export; and

(b) the security of the goods is appropriate to the level of risk that the goods could pose to the public and the environment; and

(c) the integrity of the condition of the goods is maintained.

8 Disposal of unused emergency goods — supply

(1) This clause applies to unused emergency goods that 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):

(a) registered goods or listed goods; or

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

(c) goods that are the subject of an approval under section 19A of the Act.

(2) The Secretary may direct that the goods 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

(b) to whom the approval or authority under section 19 of the Act is given; or

(c) to whom the approval under section 19A of the Act is given.

9 Owner to be paid for goods supplied

A direction given under clause 7 or 8 does not affect a person's liability to pay the owner of the goods for the export or supply of the goods to the person.

10 Records about unused emergency goods

A person who has, or has had, control over unused emergency goods must:

(a) ensure that records are kept that include the following information:

(i) the quantities of the goods under the person's control;

(ii) how the goods 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 as directed and when the actions were taken;

(iv) if the goods 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 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 has not complied with a provision of this Schedule, the Secretary may destroy the goods.

Schedule 6 Therapeutic devices prescribed for the purposes of paragraph 26 (1) (g) of the Act

(regulation 16)

Column 1 Item No.	Column 2 Device
1	therapeutic devices supplied as pharmaceutical benefits
2	therapeutic devices that are required to be, or that are represented to be, sterile
3	therapeutic devices that are not sterile and do not contain or include any sterile component or portion and that are: (a) devices for use in contraception or in the prevention of transmission of disease between persons; or (b) dental restorative materials; or (c) bandages, dressings, adhesive tapes and similar products (other than casting materials), required to be sterile and to be supplied in accordance with criteria prescribed under paragraph 26 (1) (k) of the Act; or (d) soft contact lenses; or (e) lubricants for insertion into body cavities or orifices; or (f) diagnostic goods for *in vitro* use that are: (i) goods for home use; or (ii) goods that incorporate material of human origin; or (g) implantable therapeutic devices
3A	non-sterile preserved multi-use gel wound dressings (*hydrogels*)
4	a container of a kind referred to in item 5 of Schedule 7

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

(regulation 17)

Column 1 Item No.	Column 2 Therapeutic goods
1	goods prepared for the initial experimental studies in human volunteers
2	ingredients, except water, used in the manufacture of therapeutic goods where the ingredients: (a) do not have a therapeutic action; or (b) are herbs, bulk hamamelis water or oils extracted from herbs, the sole therapeutic use of which is as starting materials for use by licensed manufacturers
3	components for therapeutic devices
4	therapeutic devices that are not sterile and do not contain or include any sterile component or portion, other than: (a) devices for use in contraception or prevention of transmission of disease between persons; or (b) dental restorative materials; or (d) soft contact lenses; or (e) lubricants for insertion into body cavities or orifices; or (f) any other devices included in Schedule 3; or (g) diagnostic goods for *in vitro* use that are: (i) goods for home use; or (ii) goods that incorporate material of human origin; or (h) implantable therapeutic devices

Column 1 Item No.	Column 2 Therapeutic goods
5	containers other than: (a) sterile syringes; or (b) single use containers designed for the collection, storage and transfer of blood for diagnostic testing (other than single use containers recommended by the manufacturer to be used only in equipment measuring the physical properties of blood) (c) containers designed for the collection of blood for transfusion; or (d) containers designed for the collection of blood for use in the manufacture of blood products; or (e) containers designed for the storage of blood and blood components for parenteral administration; or (f) containers, not made of glass, designed for the storage and parenteral administration of therapeutic goods (commonly referred to as “large volume parenteral infusion bags”); or (g) bags designed for the collection of fluids drained from the body of a patient (commonly referred to as “drainage bags”)
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

Column 1 Item No.	Column 2 Therapeutic goods
13	disinfectants, except instrument grade disinfectants, that are represented to be sterilants, fungicides, sporicides, tuberculocides or virucides when used as recommended by the manufacturers on a critical medical device or a semi-critical medical device
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 2604:1998, 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

Column 1 Item No.	Column 2 Therapeutic goods
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 1 Item	Column 2 Persons	Column 3 Matter in relation to which person exempted
1	medical practitioners, dentists and other health care workers registered under a law of a State or Territory	the manufacture of: (a) 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 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

Column 1 Item	Column 2 Persons	Column 3 Matter in relation to which person exempted
3	biomedical engineers, radiochemists and pharmacists in public hospitals	the manufacture of therapeutic goods 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 or the registration or listing number of goods

Column 1 Item	Column 2 Persons	Column 3 Matter in relation to which person exempted
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

(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.

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 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 1 Item	Column 2 Matter	Column 3 Fee
		$
1A	application fee for processing an application for consent under section 14 of the Act	300
1	evaluation fee for the purposes of subparagraph 19 (2) (b) (iii) of the Act:	
	(a) if: (i) the goods are medicines for use solely for experimental purposes in humans; and (ii) the evaluation consists of the consideration of: (A) a summary of chemical, pharmaceutical and biological information about the goods; and (B) descriptive information about the proposed clinical trial of the goods; and (C) information about adverse events associated with the use of the goods; and (D) information about the goods provided to the relevant ethics committee; — for each medicine	1 240
	(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	15 300

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
	(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	12 100
	(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	1 820
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	780
	(b) for an application relating to a therapeutic device of a kind mentioned in Part 2 of Schedule 3	960
	(ba) for an application relating to a medicine to which item 4 applies, if: (i) the Secretary considers that the application cannot be determined because of insufficiency of information delivered (Act, paragraph 23 (2) (b)); or (ii) the application is withdrawn before notification of acceptance is sent under subregulation 16B (1)	5 850; or 20% of the relevant fee under item 4; whichever is the less

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
	(c) subject to paragraph (d), for an application in any other case	2 900
	(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	1 450 — for each additional application, up to a maximum amount payable of $8 440 (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	340
	(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	960

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
	(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	490
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	670
2A	fee for varying an entry in the Register (not including evaluation of data) under subsection 9D (1), (2) or (3) of the Act, if the variation is for:	
	(a) a registered medicine that is mentioned in Part 1 of Schedule 10 — for each submission	1 300
	(b) a registered medicine that is mentioned in Part 2 or Part 3 of Schedule 10	780
	(c) a listed medicine	240
	(d) a registered therapeutic device that is mentioned in Part 2 of Schedule 3	490
	(e) a registered therapeutic device, other than a device mentioned in paragraph (d)	960
	(f) a listed therapeutic device	300
	(g) a medical device	300

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
2B	fee for an application to which regulation 16F or 16G applies, for evaluation of the chemistry, quality control or manufacturing process of the medicine — for each submission	4 280
2C	fee for an application under subsection 9D (1), (2) or (3) of the Act (other than an application to which item 4 applies), for evaluation of clinical, pre-clinical or bioequivalence data, or the chemistry, quality control or manufacturing process, of the goods	4 280
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	300
	(b) a medicine	490
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	340
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
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

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
	(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 (if paragraph (ba) of item 2 does not apply) for evaluation relating to:	
	(a) a new chemical entity (other than an entity to which paragraph (aa) applies)	189 900
	(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	one-third of the fee specified in paragraph (a)
	(ii) documentation relating to pre-clinical studies; or	one-third of the fee specified in paragraph (a)
	(iii) documentation mentioned in subparagraphs (i) and (ii)	two-thirds of the fee specified in paragraph (a)
	(b) an extension of indications (other than an extension of indications to which paragraph (bb) applies)	112 900

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
	(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:	
	(i) documentation setting out the chemistry, quality control and manufacturing of the medicine; or	one-third of the fee specified in paragraph (b) or (g) for an evaluation of that nature
	(ii) documentation relating to pre-clinical studies; or	one-third of the fee specified in paragraph (b) or (g) for an evaluation of that nature
	(iii) documentation mentioned in subparagraphs (i) and (ii)	two-thirds of the fee specified in paragraph (b) or (g) for an evaluation of that nature
	(c) a new generic product	67 000
	(d) an additional trade name	11 900
	(e) a change to product information	4 280
	(f) a change to consumer patient information	1 300
	(g) a major variation (that is not a variation mentioned in any of paragraphs (a) to (f))	73 600
	(h) a minor variation (that is not a variation mentioned in any of paragraphs (a) to (f))	4 280

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
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	5 190
	(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:	
	(i) not over 50 pages	5 190
	(ii) over 50 pages, but not over 250 pages	6 640
	(iii) over 250 pages, but not over 500 pages	9 060
	(iv) over 500 pages, but not over 1,000 pages	12 060
	(v) over 1,000 pages, but not over 2,000 pages	18 100
	(vi) over 2,000 pages, but not over 3,000 pages	24 200
	(vii) over 3,000 pages	36 200
	(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	1 870

Column 1 Item	Column 2 Matter		Column 3 Fee
			$
	(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	1 870
		(ii) over 50 pages, but not over 250 pages	6 640
		(iii) over 250 pages, but not over 500 pages	9 060
		(iv) over 500 pages, but not over 1,000 pages	12 100
		(v) over 1,000 pages, but not over 2,000 pages	18 100
		(vi) over 2,000 pages, but not over 3,000 pages	24 200
		(vii) over 3,000 pages	36 200
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	3 630
	(b)	manufacture, quality control or sterile manufacture, or testing information	3 630
	(c)	biocompatability or preclinical information	3 630
	(d)	software	3 630
	(e)	human clinical information	3 630
	(f)	control material for use with diagnostic goods for *in vitro* use	3 630

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
5B	evaluation fee for subsection 24 (1) of the Act in respect of disinfectants or diagnostic goods for *in vitro* use	12 100
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	21 300
	(b) manufacture, quality control or sterile manufacture or testing information;	14 500
	(c) biocompatability or pre-clinical information;	14 500
	(ca) software;	14 500
	(d) human clinical information	24 200
6AA	fee for evaluation 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:	250
	(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	
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)	220

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
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 item 6AA)	780
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	14 500
	(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	3 630
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	960
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	2 420
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)	4 830

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
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	5 190
	(b) over 50 pages, but not over 250 pages	6 640
	(c) over 250 pages, but not over 500 pages	9 060
	(d) over 500 pages, but not over 1 000 pages	12 100
	(e) over 1 000 pages, but not over 2 000 pages	18 100
	(f) over 2 000 pages, but not over 3 000 pages	24 200
	(g) over 3 000 pages	36 200
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	7 240
	(b) manufacturing, quality control and sterile manufacture or testing information;	6 040
	(c) biocompatability or pre-clinical information;	6 040
	(ca) software;	6 040
	(d) human clinical information	24 200
	(e) confirmatory review of clinical information	6 040
	(f) confirmatory evaluation of overseas reports or data	6 040
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:	

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
	(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	5 190
	(b) if the evaluation documentation contains clinical or toxicological information, and the total number of pages is:	
	(i) not over 50 pages	5 190
	(ii) over 50 pages, but not over 250 pages	6 640
	(iii) over 250 pages, but not over 500 pages	9 060
	(iv) over 500 pages, but not over 1,000 pages	12 100
	(v) over 1,000 pages, but not over 2,000 pages	18 100

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
	(vi) over 2,000 pages, but not over 3,000 pages	24 200
	(vii) over 3,000 pages	36 200
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	5 190
	(b) if the evaluation documentation contains clinical or toxicological information, and the total number of pages is:	
	(i) not over 50 pages	5 190
	(ii) over 50 pages, but not over 250 pages	6 640
	(iii) over 250 pages, but not over 500 pages	9 060
	(iv) over 500 pages, but not over 1,000 pages	12 100
	(v) over 1,000 pages, but not over 2,000 pages	18 100
	(vi) over 2,000 pages, but not over 3,000 pages	24 200
	(vii) over 3,000 pages	36 200
8	application fee for the purposes of paragraph 37 (1) (g) of the Act	670
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 9AB, 9AC and 9ACA), per hour, per inspector, for:	430
	(i) the manufacture of therapeutic goods; or	

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
	(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)	900
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 under licence, at the primary site covered by the licence, for each inspector engaged per hour, or part of an hour	600
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 and blood components under licence, at a site covered by the licence other than the primary site, for each inspector engaged per hour, or part of an hour	430
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	430

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
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	880
	(b) over 10 pages, but not over 50 pages	7 490
	(c) over 50 pages, but not over 100 pages	16 600
	(d) over 100 pages, but not over 1 000 pages	22 400
	(e) over 1 000 pages, but not over 3 000 pages	35 000
	(f) over 3 000 pages, but not over 4 000 pages	46 500
	(g) over 4 000 pages	56 700
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	12 100
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	12 100
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):	

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
	(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	90 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	The fee applicable under item 1, 4, 5, 6 or 7 for an evaluation of that nature

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
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	240
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)	240
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

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
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	140
	(ii) of more than 100 words	180
	(iii) of more than 300 words (including an advertorial)	310
	(iv) that is intended for publication in the classified advertisement columns of a newspaper or other publication	70
	(b) if the time needed to process the application is more than an hour	The fee applicable under paragraph (a) plus $120 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	70
	(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,

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
		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	800
	(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	400
	(iii) a television advertorial of more than 150 seconds:	
	(A) for the first minute of each script	600
	(B) for each additional minute or part of a minute of each script	150
	(iv) a radio advertisement, including up to 6 variations of the advertising concept for the same product	290
	(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	190

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
	(vi) a still cinema media advertisement (including outdoor media):	
	(A) of not more than 100 words	140
	(B) of not more than 300 words	180
	(C) of more than 300 words	310
	(b) if the time needed to process the application is more than an hour	The fee applicable under paragraph (a) plus $120 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	10 300

Schedule 10 Therapeutic goods for evaluation

(subregulations 16C (1), 16D (1), 16F (1) and 16G (1))

Part 1 Evaluation by the Drug Safety and Evaluation Branch of the Department

Column 1 Item	Column 2 Product
1	therapeutic goods (except therapeutic goods mentioned in another Part of this Schedule), that: (a) contain a substance mentioned in Schedule 4, 8 or 9 to the Poisons Standard; or (b) contain a substance not mentioned in any of those Schedules but which meets the criteria for mention in any of those Schedules
2	a medical gas
3	a vaccine
4	an allergen, except an allergen for skin patch testing on unbroken skin
5	a biotechnology medicine
6	an immunoglobulin
7	a radio contrast agent, except barium sulphate preparation for radiological use
8	a radiopharmaceutical
9	a dialysis solution, except a haemodialysis solution
11	a special dosage form, such as a transdermal system or osmotic pump
12	an injectable medicine dosage form
13	a blood product, unless coated on a therapeutic device
14	therapeutic goods referred for evaluation to the Drug Safety and Evaluation Branch of the Therapeutic Goods Administration within the Department

Column 1 Item	Column 2 Product
15	an excipient in therapeutic goods mentioned in this Part
16	a therapeutic device that depends upon the release of a substance for some or all of its action

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 1 Item	Column 2 Product
1	a complementary medicine
2	an excipient in complementary medicine
3	therapeutic goods referred for evaluation to the Complementary Medicines Section of the Therapeutic Goods Administration within the Department

Part 3 Evaluation by OTC Medicine Evaluation Section of the Department

The following therapeutic goods, if the sponsor has satisfied the Secretary that the goods do not meet the criteria for mention in Schedule 4, 8 or 9 of the Poisons Standard:

Column 1 Item	Column 2 Product
1	an antiseptic
2	a sunscreen preparation
3	all other therapeutic goods, except a therapeutic device, not mentioned in another Part of this Schedule
4	an excipient in therapeutic goods mentioned in this Part

Column 1 Item	Column 2 Product
5	therapeutic goods referred for evaluation to the Scheduling and Over-the-counter Drug Evaluation Section of the Therapeutic Goods Administration within the Department

Schedule 11 Criteria prescribed under paragraph 26 (1) (k) of the Act

(subregulation 16 (2))

Part 1 Therapeutic goods for which quality or safety criteria are prescribed

Column 1 Item	Column 2 Kind of goods
1	Primary dressings, for wounds, burns or broken skin, that are: (a) plain dressings; or (b) adhesive dressings; or (c) "combine" dressings; or (d) impregnated dressings; or (e) gauzes; or (f) wound closures other than dressings that are: (g) adhesive dressing strips, or combine dressings, supplied in bulk length for multiple use; or (h) plain gauze or other absorbent dressing pieces that are supplied in bulk packs not individually wrapped
2	Surgical absorbents, for use in surgical procedures or for introduction into body cavities to absorb blood or secretions, that are: (a) gauzes; or (b) sponges; or (c) swabs; or (d) x-ray detectable gauzes; or (e) x-ray detectable sponges
2A	non-sterile preserved multi-use gel wound dressings (*hydrogels*)

Column 1 Item	Column 2 Kind of goods
3	Goods supplied as sterile, and "sterile labelled", that are: (a) absorbents; or (b) adhesive tapes (c) bandages; or (d) dressings; or (e) gauzes; or (f) stockinets; or (g) undercast padding

Part 2 Quality and safety criteria

Column 1 Item	Column 2 Criteria
1	Except as provided by another item, the goods must be sterile
2	In the case of non-sterile goods supplied in bulk otherwise than to consumers — the goods must comply with quality and safety criteria approved by the Secretary for the purposes of this item
3	For non-sterile preserved multi-use gel wound dressings (*hydrogels*), the following criteria apply: (a) the total aerobic microbial count (TAMC) must not exceed 10 CFU per g or per mL and the goods must be free of Pseudomondas, S. *aureus* and gram negative organisms; (b) compliance with paragraph (a) must be shown by a certificate signed by an appropriately qualified analyst stating in English: (i) the test method; and (ii) if the test method is not a recognised pharmacopeial test method — full details of the test method; and (iii) the date of testing (which must be not earlier that 6 months before retail supply);

Column 1 Item	Column 2 Criteria
	(c) the labelling on the primary pack must include a statement that, after a dressing has been used by a patient, it must not be used by another patient, or words to that effect; *Note* For ***label*** and ***primary pack***, see Act, subs 3 (1). (d) the labelling must state an expiry date and an open shelf life for the goods, both of which must be supported by data about the efficacy of preservatives used in the goods; *Note* For ***expiry date*** and ***open shelf life***, see r 2. (e) the goods must not be represented: (i) for use in the treatment of third degree burns; or (ii) as having an accelerating effect on the rate of wound healing or epithelisation; or (iii) as long term, permanent or no-change dressings or as an artificial (synthetic) skin.

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 (within the meaning of section 9D of the Act) 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 (within the meaning of section 9D of the Act) 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

(Act, section 52F)

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

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 1990 No. 394 amended as indicated in the Tables below.

For application, saving or transitional provisions *see* Table A.

Table of Statutory Rules

Year and number	Date of notification in *Gazette*	Date of commencement	Application, saving or transitional provisions
1990 No. 394	6 Dec 1991	15 Feb 1991	
1991 No. 84	30 Apr 1991	Rr. 3.1, 5.2, 7.1, 10.2, 11.1, 12.2, 12.4, 13.1 and 14.1: 15 Feb 1991 Remainder: 30 Apr 1991	—
1991 No. 485	24 Dec 1991	24 Dec 1991	—
1992 No. 19	31 Jan 1992	R. 10: 1 July 1992 Remainder: 1 Feb 1992	—
1992 No. 89	14 Apr 1992	14 Apr 1992	—
1992 No. 109	28 Apr 1992	28 Apr 1992	—
1992 No. 332	27 Oct 1992	27 Oct 1992	—
1992 No. 370	30 Nov 1992	30 Nov 1992	—
1992 No. 430	24 Dec 1992	Rr. 4 and 7: 1 Jan 1993 Remainder: 24 Dec 1992	—
1993 No. 141	25 June 1993	1 July 1993	—
1994 No. 150	2 June 1994	2 June 1994	R. 22
1994 No. 222	30 June 1994	1 July 1994	—
1994 No. 364	1 Nov 1994	1 Nov 1994	—
1995 No. 33	8 Mar 1995	8 Mar 1995	—
1995 No. 111	31 May 1995	1 June 1995	—
1995 No. 192	30 June 1995	1 July 1995	—

Table of Statutory Rules

Year and number	Date of notification in *Gazette*	Date of commencement	Application, saving or transitional provisions
1995 No. 208	4 July 1995	Rr. 6 and 9.3: 1 Oct 1995 Rr. 8, 9.2, 10.6 and 11.7: 1 Jan 1996 R. 10.7: 1 Oct 1996 Rr. 13.2 and 14.4: 1 Jan 1997 Remainder: 4 July 1995	R. 19
1995 No. 253	29 Aug 1995	29 Aug 1995	—
1995 No. 320	3 Nov 1995	3 Nov 1995	—
1995 No. 328	3 Nov 1995	6 Nov 1995 (*see* r. 1 and *Gazette* 1995, No. S423)	—
1996 No. 9	31 Jan 1996	31 Jan 1996	—
1996 No. 25 *(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 1997 Remainder: 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 2000 Remainder: 31 Mar 2000	—
2000 No. 48	19 Apr 2000	19 Apr 2000	—
2000 No. 70	12 May 2000	1 July 2000	—
2000 No. 123	22 June 2000	22 June 2000	—
2000 No. 124	22 June 2000	1 July 2000	—
2000 No. 267	28 Sept 2000	28 Sept 2000	—
2000 No. 358	20 Dec 2000	20 Dec 2000	—
2001 No. 159	29 June 2001	29 June 2001	—

Table of Statutory Rules

Year and number	Date of notification in *Gazette*	Date of commencement	Application, saving or transitional provisions
2001 No. 160	29 June 2001	1 July 2001	—
2001 No. 252	20 Sept 2001	22 Sept 2001 (*see* r. 2)	—
2001 No. 343	21 Dec 2001	Rr. 1–3 and Schedule 1: 30 Sept 2001 Remainder: 21 Dec 2001	—
2002 No. 9	21 Feb 2002	21 Feb 2002	—
2002 No. 84	9 May 2002	9 May 2002	—
2002 No. 114	7 June 2002	7 June 2002	—
2002 No. 143	27 June 2002	1 July 2002	—
2002 No. 234	4 Oct 2002	4 Oct 2002 (*see* r. 2)	—
2002 No. 315	19 Dec 2002	Rr. 1–3 and Schedule 1: 19 Dec 2002 Remainder: 1 Jan 2003	—
2002 No. 345	20 Dec 2002	Rr. 1–3 and Schedule 1: 20 Dec 2002 Remainder: 1 Jan 2003	—
2003 No. 111	13 June 2003	13 June 2003	—
2003 No. 151	26 June 2003	1 July 2003	—
2003 No. 257	16 Oct 2003	16 Oct 2003	—
2003 No. 258	16 Oct 2003	Rr. 1–3 and Schedule 1: 16 Oct 2003 Remainder: 1 Oct 2004	—
2003 No. 301	5 Dec 2003	5 Dec 2003	—
2003 No. 361	23 Dec 2003	23 Dec 2003	—
2004 No. 78	30 Apr 2004	30 Apr 2004	—
2004 No. 127	18 June 2004	1 July 2004	R. 4
2004 No. 159	25 June 2004	1 July 2004	—

(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
Note to r. 2	ad. 1999 No. 62
R. 2A	ad. 2003 No. 361
R. 3	am. 1992 No. 89; 1992 No. 430 rs. 1995 No. 111 am. 1996 No. 200 rs. 2003 No. 361
R. 3A	ad. 2003 No. 301
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

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
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
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. 6A	ad. 1995 No. 208 rs. 2003 No. 301
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
R. 8A	ad. 2003 No. 301

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
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
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)	
R. 10B (formerly r. 14)	
R. 10C (formerly r. 14A)	
R. 10D	ad. 2002 No. 234
Division 2C.2	
R. 10E	ad. 2002 No. 234

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
R. 10F	ad. 2002 No. 234
Part 3	
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
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
Heading to r. 12A	am. 1999 No. 62
R. 12A	ad. 1991 No. 485 am. 1999 No. 62; 2000 No. 358; 2002 Nos. 9 and 234
R. 12AAA	ad. 2003 No. 111
R. 12AAB	ad. 2003 No. 111
R. 12AA	ad. 2000 No. 358
R. 12AB	ad. 2000 No. 358 am. 2003 Nos. 258 and 361
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
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
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
R. 15A	ad. 2003 No. 258
R. 16	am. 1992 No. 89
R. 16AA	ad. 2003 No. 151

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
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
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 am. 2003 No. 151
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
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; 2003 No. 361
R. 24	am. 1991 No. 84; 2002 No. 234; 2004 No. 78

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
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
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 6	
Division 1	
Heading to Div. 1 of Part 6	ad. 1997 No. 400 rs. 2002 No. 234
R. 34	am. 1995 No. 208; 1999 No. 62; 2002 No. 234
R. 35	am. 1991 No. 485; 1999 No. 62 rs. 2002 No. 234
R. 36	am. 1991 No. 485; 1999 No. 62; 2002 No. 234
R. 37	am. 1997 No. 400
R. 38	am. 1991 No. 485; 1997 No. 400; 2002 No. 234
R. 39	am. 1997 No. 400
R. 40	am. 1997 No. 400
R. 41	am. 1991 No. 485; 1997 No. 400; 2002 No. 234
R. 42	am. 1997 No. 400
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
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

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
R. 42J	ad. 1997 No. 400 am. 2000 No. 48; 2001 No. 159; 2002 No. 315; 2003 Nos. 258 and 361
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
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
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 rs. 2003 No. 301
R. 42Z	ad. 1997 No. 400
R. 42ZA	ad. 1997 No. 400
R. 42ZB	ad. 1997 No. 400
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
Note to r. 42ZCAA	rep. 2001 No. 159

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
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. 42ZCAH	ad. 2000 No. 48
R. 42ZCAI	ad. 2000 No. 48 am. 2002 Nos. 234 and 315; 2003 No. 301
R. 42ZCAJ	ad. 2000 No. 48
R. 42ZCAK	ad. 2000 No. 48
R. 42ZCAL	ad. 2002 No. 315
Division 3A	
Div. 3A of Part 6	ad. 1999 No. 209
Subdivision 1	
R. 42ZCA	ad. 1999 No. 209
Subdivision 2	
R. 42ZCB	ad. 1999 No. 209
Subdivision 3	
R. 42ZCC	ad. 1999 No. 209
R. 42ZCD	ad. 1999 No. 209
R. 42ZCE	ad. 1999 No. 209
R. 42ZCF	ad. 1999 No. 209
R. 42ZCG	ad. 1999 No. 209
R. 42ZCH	ad. 1999 No. 209
R. 42ZCI	ad. 1999 No. 209
R. 42ZCJ	ad. 1999 No. 209
R. 42ZCK	ad. 1999 No. 209
R. 42ZCL	ad. 1999 No. 209
Subdivision 4	
R. 42ZCM	ad. 1999 No. 209
R. 42ZCN	ad. 1999 No. 209
R. 42ZCO	ad. 1999 No. 209
R. 42ZCP	ad. 1999 No. 209
R. 42ZCQ	ad. 1999 No. 209
R. 42ZCR	ad. 1999 No. 209
R. 42ZCS	ad. 1999 No. 209

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
Subdivision 5	
R. 42ZCT	ad. 1999 No. 209
R. 42ZCU	ad. 1999 No. 209
R. 42ZCV	ad. 1999 No. 209
R. 42ZCW	ad. 1999 No. 209
R. 42ZCX	ad. 1999 No. 209
R. 42ZCY	ad. 1999 No. 209
R. 42ZCZ	ad. 1999 No. 209
R. 42ZCZA	ad. 1999 No. 209
R. 42ZCZB	ad. 1999 No. 209
Division 4	
Div. 4 of Part 6	ad. 1999 No. 62
Subdivision 1	
Subdiv. 1 of Div. 4 of Part 6	ad. 1999 No. 62
R. 42ZD	ad. 1999 No. 62
Subdivision 2	
Subdiv. 2 of Div. 4 of Part 6	ad. 1999 No. 62
R. 42ZE	ad. 1999 No. 62 am. 2000 No. 29
R. 42ZF	ad. 1999 No. 62 am. 2000 No. 29
R. 42ZG	ad. 1999 No. 62
R. 42ZH	ad. 1999 No. 62
R. 42ZI	ad. 1999 No. 62
Subdivision 3	
Subdiv. 3 of Div. 4 of Part 6	ad. 1999 No. 62
R. 42ZJ	ad. 1999 No. 62
R. 42ZK	ad. 1999 No. 62
R. 42ZL	ad. 1999 No. 62
R. 42ZM	ad. 1999 No. 62
R. 42ZN	ad. 1999 No. 62 am. 2000 No. 29
R. 42ZO	ad. 1999 No. 62
R. 42ZP	ad. 1999 No. 62
R. 42ZQ	ad. 1999 No. 62 am. 2000 No. 29
R. 42ZR	ad. 1999 No. 62

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
R. 42ZS	ad. 1999 No. 62
Subdivision 4	
Subdiv. 4 of Div. 4 of Part 6	ad. 1999 No. 62
R. 42ZT	ad. 1999 No. 62
R. 42ZU	ad. 1999 No. 62
R. 42ZV	ad. 1999 No. 62
R. 42ZW	ad. 1999 No. 62
R. 42ZX	ad. 1999 No. 62 am. 2000 No. 29
R. 42ZY	ad. 1999 No. 62
R. 42ZZ	ad. 1999 No. 62
Division 5	
Div. 5 of Part 6	ad. 2000 No. 29
Subdivision 1	
Subdiv. 1 of Div. 5 of Part 6	ad. 2000 No. 29
R. 42ZZA	ad. 2000 No. 29
Subdivision 2	
Subdiv. 2 of Div. 5 of Part 6	ad. 2000 No. 29
R. 42ZZB	ad. 2000 No. 29
Subdivision 3	
Subdiv. 3 of Div. 5 of Part 6	ad. 2000 No. 29
R. 42ZZC	ad. 2000 No. 29
R. 42ZZD	ad. 2000 No. 29
R. 42ZZE	ad. 2000 No. 29
R. 42ZZF	ad. 2000 No. 29
R. 42ZZG	ad. 2000 No. 29
Subdivision 4	
Subdiv. 4 of Div. 5 of Part 6	ad. 2000 No. 29
R. 42ZZH	ad. 2000 No. 29
R. 42ZZI	ad. 2000 No. 29
R. 42ZZJ	ad. 2000 No. 29 am. 2003 No. 258
R. 42ZZK	ad. 2000 No. 29
R. 42ZZL	ad. 2000 No. 29
R. 42ZZM	ad. 2000 No. 29

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
R. 42ZZN	ad. 2000 No. 29
R. 42ZZO	ad. 2000 No. 29
R. 42ZZP	ad. 2000 No. 29
R. 42ZZQ	ad. 2000 No. 29
Subdivision 5	
Subdiv. 5 of Div. 5 of Part 6	ad. 2000 No. 29
R. 42ZZR	ad. 2000 No. 29
R. 42ZZS	ad. 2000 No. 29
R. 42ZZT	ad. 2000 No. 29
R. 42ZZU	ad. 2000 No. 29
R. 42ZZV	ad. 2000 No. 29
R. 42ZZW	ad. 2000 No. 29
R. 42ZZX	ad. 2000 No. 29
Part 7	
Heading to Part 7	rs. 1991 No. 84
R. 43	am. 2003 No. 151
R. 43A	ad. 1994 No. 222 am. 2002 No. 234
R. 43AA	ad. 1992 No. 19
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
R. 45AA	ad. 1995 No. 192 am. 2002 No. 234
Heading to r. 45A	am. 1997 No. 162 rs. 2001 No. 160; 2003 No. 151; 2004 No. 159
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
Part 8	
R. 46A	ad. 1992 No. 332
R. 46	am. 1991 No. 84; 1992 No. 332; 1997 No. 399; 1999 No. 62; 2002 No. 234
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
R. 47A	ad. 1991 No. 485
R. 47AA	ad. 2000 No. 358 rep. 2003 No. 361

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
Heading to r. 47B	am. 1999 No. 62 rs. 2002 No. 234
R. 47B	ad. 1991 No. 485 am. 1999 No. 62 rs. 2000 No. 358 am. 2002 No. 234
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
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
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
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
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
Schedule 5	
Heading to Schedule 5	am. 2002 No. 234
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
Schedule 5A	
Heading to Schedule 5A	am. 2002 No. 234

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
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
Schedule 5B	
Schedule 5B	ad. 2003 No. 111
Schedule 6	
Schedule 6.....	am. 1992 Nos. 19, 89 and 370; 1994 No. 150; 1995 No. 208; 1997 No. 398; 1999 No. 324
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
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
Schedule 9	
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
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
Schedule 11	
Schedule 11.....	ad. 1992 No. 89 am. 1999 No. 324; 2002 No. 84
Schedule 12	
Schedule 12.....	ad. 1992 No. 430 am. 1995 No. 208; 2001 No. 159; 2003 No. 151
Schedule 13	
Schedule 13.....	ad. 1995 No. 208 am. 2001 No. 159; 2003 No. 151

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
Schedule 14	
Heading to Schedule 14.....	am. 1999 No. 62
Schedule 14.....	ad. 1997 No. 400 rs. 1998 No. 227

Note 2

Regulation 6A — Schedule 2 of the *Therapeutic Goods Amendment Regulations 2003 (No. 4)* (2003 No. 258) provides as follows:

[1] Regulation 6A

omit

For the purposes

insert

(1) For the purposes

[2] Regulation 6A

insert

(2) For the purposes of 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.

The proposed amendments were misdescribed and are not incorporated in this compilation.

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.