AUSTRALIA

Statutory Rules 1990 No. 4

394/

Therapeutic Goods Regulations

TABLE OF PROVISIONS

(S.R. 355/90)—Cat. No. 14/26.11.1990

TABLE OF PROVISIONS—*continued*

TABLE OF PROVISIONS—*continued*

Statutory Rules 1990 No. L 394

Therapeutic Goods Regulations

I, THE GOVERNOR-GENERAL of the Commonwealth of Australia, acting with the advice of the Federal Executive Council and under section 4 of the *Acts Interpretation Act 1901*, hereby make the following Regulations under the *Therapeutic Goods Act 1989*.

Dated 29 November 1990.

BILL HAYDEN

Governor-General

By His Excellency's Command,

Michael Tate.

Minister of State for Justice and Consumer Affairs for and on behalf of the Minister of State for Aged, Family and Health Services

PART 1—PRELIMINARY

Citation

1. These Regulations may be cited as the Therapeutic Goods Regulations.

Interpretation

2. In these Regulations, unless the contrary intention appears:

"analysis" includes examination and testing;

"antiseptic" means a substance that is intended for application on the body or the mucous membranes of a person or an animal

394/

to kill or prevent the growth of a broad range of micro organisms, and that is:

(a) not represented to be suitable for internal use; and

(b) not capable of inducing resistance in micro organisms to other anti-infective agents;

"diagnostic goods for *in vitro* use" means a reagent, instrument or system that is intended to be used in the examination of specimens taken from the body of a person or animal in connection with the diagnosis of a disease, ailment or defect in, or injury to, a person or animal or the monitoring of a condition in a person or animal;

"disinfectant" means a substance that is intended for application to inanimate objects to kill a broad range of micro organisms, and that is:

(a) not represented to be suitable for the internal use in, or dermal use on, a person or an animal; and

(b) not capable of inducing resistance in micro organisms to other anti-infective agents;

"drugs" means:

(a) therapeutic goods that are represented to achieve, or are likely to achieve, any of the principal purposes of their use as a result of chemical action in or on the body of a person or animal; and

(b) any other therapeutic goods declared by the Secretary, by notice published in the *Gazette*, not to be therapeutic devices;

"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;

"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;

"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;

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

"official analyst" means a person approved by the Secretary under regulation 25;

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

"poison" means a substance or preparation that is included in a Schedule to the Poisons Standard;

"Poisons Standard" means the current edition of the *Standard for the uniform scheduling of drugs and poisons* published by the National Health and Medical Research Council;

"prohibited representation" means a representation referred to in subregulation 8 (1);

"required representation" means a representation referred to in subregulation 8 (2);

"sample" includes part of a sample;

"the Act" means the *Therapeutic Goods Act 1989*;

"Therapeutic Goods Advertising Code" means the code known by that name:

(a) authorised by the Trade Practices Commission; and

(b) that had effect on 1 October 1990; and

(c) copies of which are available from the Department;

together with any amendments of that code that are approved by the Media Council of Australia and published by the Secretary in the *Gazette* as forming part of that code.

394

State or Territory laws that continue to apply

3. (1) For the purposes of subsection 6 (3) of the Act, the following laws are identified:

(a) laws of the State of New South Wales:

(i) the Therapeutic Goods and Cosmetics Act 1972:

(ii) the Therapeutic Goods and Cosmetics Regulations;

(iii) the Poisons Act 1966:

(iv) the Poisons Regulations:

(b) laws of the State of Victoria:

(i) the *Health Act* 1958;

(ii) the Health (Proprietary Medicines) Regulations 1984;

(iii) the *Drugs, Poisons and Controlled Substances Act* 1981;

(iv) the Drugs, Poisons and Controlled Substances Regulations 1985;

(c) laws of the State of Queensland:

(i) the *Health Act of 1937-1989*:

(ii) the Poisons Regulations of 1973:

(iii) the Therapeutic Goods and Other Drugs Regulations 1982;

(d) laws of the State of South Australia:

(i) the *Drugs Act, 1908*;

(ii) the *Controlled Substances Act, 1984*;

(e) laws of the State of Western Australia:

(i) the *Health Act 1911*;

(ii) the Health (Drugs and Allied Substances) Regulations 1987;

(iii) the *Poisons Act 1964*;

(iv) the Poisons Regulations 1965:

(f) laws of the State of Tasmania:

(i) the *Poisons Act 1971*;

(ii) the *Poisons Regulations 1975*:

(iii) the *Poisons List Order 1984*;

(g) the *Therapeutic Goods and Cosmetics Act* of the Northern Territory of Australia:

(h) laws of the Australian Capital Territory:

(i) the *Public Health (Prohibited Drugs) Act 1957*:

(ii) the Public Health (Sale of Food and Drugs) Regulations.

(2) This regulation, unless sooner repealed, ceases to be in force at the end of 2 years after the commencement of these Regulations.

394/

PART 2—ADVERTISEMENTS

This Part not to apply to advertisements directed at health professionals etc.

4. (1) This Part does not apply to advertisements directed exclusively to:

(a) medical practitioners, psychologists, dentists, veterinary surgeons, pharmacists, physiotherapists, dietitians, scientists working in medical laboratories or nurses; or

(b) persons who are:

(i) engaged in the business of wholesaling therapeutic goods; or

(ii) purchasing officers in hospitals; or

(c) herbalists, homoeopathic practitioners, chiropractors, naturopaths, nutritionists, practitioners of traditional Chinese medicine or osteopaths registered under a law of a State or Territory.

(2) This Part does not apply to advertisements directed exclusively to persons who are members of an Australian branch (however described) of one of the bodies referred to in Schedule 1.

(3) This Part does not apply to advice or information given directly to a patient by a person referred to in paragraph (1)(a) or (c) or subregulation (2) in the course of treatment of that patient.

This Part not to apply to advertisements for goods not for human use

5. This Part does not apply to advertisements in respect of goods that are not for use in humans.

Advertising offences

6. (1) A person must not publish an advertisement about goods for therapeutic use:

(a) that contains a prohibited representation (whether in express terms or by necessary implication) about those goods; or

(b) that does not contain a required representation about those goods; or

(c) that is in contravention of a notice referred to in regulation 7 or 9:

(i) that was served on that person; or

(ii) of which the person was aware when the advertisement was published; or

(d) that contains:

(i) a reference to the Act, other than in a statement of the registration number or listing number of the goods; or

(ii) a statement suggesting or implying that the goods have been recommended or approved by or on behalf of a government or government authority, other than a statement of their availability as a pharmaceutical benefit; or

(e) that refers to goods included in Schedule 3, 4 or 8 to the Poisons Standard; or

(f) that are not registered or listed, unless the goods are exempt goods.

Penalty: $1,000.

(2) Subject to subregulation (3), in a prosecution under subsection (1), it is a defence if the defendant establishes that the contravention of that subregulation in respect of which the proceeding was instituted was due:

(a) to a reasonable mistake; or

(b) to reasonable reliance on information supplied by another person; or

(c) to the act or default of another person, to an accident or to some other cause beyond the defendant's control, and the defendant took reasonable precautions and exercised due diligence to avoid the contravention.

(3) In paragraphs (2) (b) and (c), **"another person"** does not include a person who was:

(a) a servant or agent of the defendant; or

(b) if the defendant is a body corporate—a director, servant or agent of the defendant, at the time when the contravention occurred.

(4) If a defence provided by subregulation (2) involves an allegation that a contravention was due to reliance on information supplied by another person, the defendant is not, without leave of the Court, entitled to rely on that defence unless he or she has, not later than 7 days before the day on which the hearing of the proceeding commences, given the person by whom the proceeding was instituted a notice in writing setting out such information that would identify or assist in the identification of the other person as was then in his or her possession.

(5) In a proceeding under this regulation, it is a defence if the defendant establishes that:

(a) he or she is a person whose business it is to publish or arrange for the publication of advertisements: and

(b) that he or she received the advertisement for publication in the ordinary course of business; and

(c) that he or she did not know and had no reason to suspect that its publication would amount to a contravention of subregulation (1).

Certain representations not to be published

7. If a representation in an advertisement about therapeutic goods is false or misleading, the Secretary may, by notice given to the person apparently responsible for publishing the advertisement, prevent that person from publishing, or causing to be published an advertisement containing that representation (whether express or implied) about those goods.

Prohibited and required representations

8. (1) For the purposes of paragraph 6 (1) (a), the representations specified in column 2 of an item in Part 1 of Schedule 2 are prohibited representations about the therapeutic goods specified in column 3 of that item.

(2) For the purposes of paragraph 6 (1) (b), a representation specified in column 2 of an item in Part 2 of Schedule 2 is a required representation about the therapeutic goods specified in column 3 of that item.

Use of prohibited representations

9. The Secretary may, by notice published in the *Gazette*, permit a prohibited representation to be included on the label of therapeutic goods, or in information included in the package in which therapeutic goods are contained, if the representation is necessary for the appropriate use of the goods.

PART 3—REGISTRATION, LISTING AND EXEMPTION OF THERAPEUTIC GOODS

Registered goods

10. For the purpose of paragraph 17 (4) (a) of the Act, the therapeutic goods, or classes of therapeutic goods, specified in Schedule 3 must be included in the part of the Register for registered goods.

Listed goods

11. For the purposes of paragraph 17 (4) (a) of the Act, the therapeutic goods, or classes of therapeutic goods, specified in Part 1 of Schedule 4 must be included in the part of the Register for listed goods.

Exempt goods

12. (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 of the Act.

(2) If:

(a) therapeutic goods that are exempt from the operation of Part 3 of the Act cease to be exempt; and

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

the goods are regarded as being exempt until the application for registration or listing is determined.

Change of person in whose name goods are registered or listed

13. (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.

(5) When a person notifies the Secretary of an event referred to in paragraph (1) (b), (2) (b), (3) (b) or (4) (d), 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 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 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 for an offence against this subregulation: $500.

Transfers within the Register

14. (1) If goods 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: $500.

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

Application of registration or listing number to goods

15. For the purposes of paragraph 20 (2) (d) 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 drugs—by writing the number on the label on the container of the drugs, or, if the container is enclosed in a primary pack for supply, on the label on that primary pack; and

(c) 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.

Listing of certain therapeutic devices

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

PART 4—LICENSING OF MANUFACTURERS

Exempt goods for the purposes of subsection 34 (1) of the Act

17. For the purposes of subsection 34 (1) of the Act, the therapeutic goods specified in Schedule 7 are exempt from the operation of Part 4 of the Act unless the goods are supplied as pharmaceutical benefits.

Exempt Persons

18. 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 4 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.

Requirements for licence holders

19. 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.

Conditions of licences

20. 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.

Persons having control of production etc. to be named

21. 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.

Transfer of licences

22. (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.

(5) When a person notifies the Secretary of an event referred to in paragraph (1) (b), (2) (b), (3) (b) or (4) (d), 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) or (4) (d) 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) or (4) (b), the Secretary may cancel the licence to which the event relates.

PART 5—EXAMINATION, TESTING AND ANALYSIS OF GOODS

Interpretation

23. In this Part, unless the contrary intention appears:

"authorised officer", in relation to a provision in this Part, means:

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

(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;

that is a Department, unit or authority the functions of which relate to health matters;

who is authorised in writing by the Secretary to exercise powers under that provision;

"relevant test", in relation to the analysis of therapeutic goods, means a test that, under regulation 28, is a relevant test for the purposes of determining whether goods of a class in which the first-mentioned goods are included are goods of a particular standard.

Authorised officer—powers and duties

24. (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 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 registration or listing of goods 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.

Appointment of official analysts

25. (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.

Taking of samples for testing

26. (1) Where an authorised officer takes a sample of therapeutic goods, 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 an official analyst 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 an official analyst.

(2) The authorised officer must ensure the sample is appropriately packaged, fastened and sealed and is to cause the sample to be stored and transported in accordance with the conditions (if any) specified on the label of the goods.

(3) For the purposes of subregulation (2), a sample is to be fastened and sealed:

(a) in a vessel or package that is marked with the name and address of the person from whom the sample was taken; and

(b) so as to prevent the opening of the vessel or package, or the removal of the name and address, without breaking the seal.

Examination and testing by official analyst

27. An official analyst must, as soon as practicable after receiving a sample of goods determine whether the sample is or has been appropriately packaged, fastened and sealed in accordance with subregulation 26 (3) and, if so:

(a) arrange for and supervise the analysis of the sample by means of relevant tests to the extent that 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 the goods from which the sample was taken comply with any standard applicable to them or with conditions relating to matters referred to in paragraph 28 (2) (d) of the Act; and

(b) arrange for the 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.

Relevant tests

28. Each of the following is a relevant test for determining whether particular therapeutic goods are of a particular standard:

(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 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.

Certificate of official analyst

29. (1) An official analyst who has arranged and supervised the analysis of a sample of goods must send to the sponsor of the goods, a certificate signed by the official analyst setting out the results of the examination and analysis.

(2) The official analyst must forward a copy of the certificate signed by the official analyst to:

(a) the Secretary; and

(b) the person from whom the sample was taken if that person was 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) A certificate referred to in subregulation (1), and the copy of it referred to in paragraph (2) (b), must be accompanied by a statement:

(a) to the effect 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; and

(b) specifying the time within which a request for a review of the results may be made; and

(c) indicating that the person may request 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.

Review of findings of official analyst

30. (1) Where:

(a) an official analyst has issued a certificate under subregulation 29 (1) stating that goods do not conform to a specified standard, or requirement, that is applicable to the goods within the meaning of regulation 27; and

(b) a person to whom the certificate, or a copy of the certificate, was issued, sends to the Secretary evidence in writing establishing that the goods do conform to that standard or requirement;

the person 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 to a particular standard 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 to the standard 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 person 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.

Payment for samples

31. (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.

(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.

Offences relating to analysis etc.

32. (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, refuse or fail, without reasonable excuse:

(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 the official analyst, refuse or fail, without reasonable excuse, 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: $1,000.

(2) It is a reasonable excuse for a person to refuse or 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.

Identity cards

33. (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 for an offence against this subregulation: $100.

PART 6—COMMITTEES

Therapeutic Goods Committee

34. (1) The Therapeutic Goods Committee is established.

(2) The functions of the Committee are:

(a) to consider any matters referred to it by the Minister relating to the administration of the Act; and

(b) to consider and inquire into:

(i) the standards applicable to any therapeutic goods and any matter relating to those standards; and

(ii) the requirements with respect to labelling and packaging of goods; and

(iii) principles to be observed in the manufacture of therapeutic goods for use in humans;

and to advise the Minister about those matters, standards, requirements and principles.

(3) The Committee consists of not fewer than 8 persons and not more than 11 persons, each of whom is to be appointed in writing by the Minister.

(4) The Committee is to consist of:

(a) persons, each of whom has expertise in one or more of the following fields:

(i) pharmaceutics;

(ii) pharmaceutical chemistry;

(iii) pharmacology;

(iv) microbiology;

(v) virology;

(vi) therapeutic devices;

(vii) veterinary science;

(viii) pharmacognosy; and

(b) 4 persons, at least one of whom has experience of each of the following kinds:

(i) scientific experience in the manufacture of pharmaceutical drugs;

(ii) scientific experience in the manufacture of alternative medicines;

(iii) scientific experience in the manufacture of therapeutic devices;

(iv) consumer affairs experience in respect of therapeutic goods; and

(c) a person nominated by the Secretary to the Department of Primary Industries and Energy.

(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.

Therapeutic Device Evaluation Committee

35. (1) The Therapeutic Device Evaluation Committee is established.

(2) The functions of the Committee are:

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

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

(c) to make medical and scientific evaluations of drugs that the Minister or the Secretary refers to it for evaluation; and

(d) to give such 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 such persons or bodies as the Minister directs.

(3) The Committee consists of not less than 6 and not more than 9 persons appointed in writing by the Minister from persons at least 6 of whom are expert in one or more of the following disciplines:

(a) anaesthetics;

(b) bioengineering;

(c) biomaterials;
(d) dentistry;
(e) epidemiology;
(f) intensive care;
(g) medicine;
(h) microbiology;
(i) ophthalmology;
(j) pharmaceutics;
(k) surgery;
(l) nursing.

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

(5) 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.

Australian Drug Evaluation Committee

36. (1) The Australian Drug Evaluation Committee is established.

(2) The functions of the Committee are:

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

(b) to make medical and scientific evaluations of other drugs 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 therapeutic devices 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) The Committee consists of not less than 6 and not more than 9 members, who are to be appointed, in writing, by the Minister.

(4) In appointing members of the Committee, the Minister is to ensure that the members include:

(a) not less than 4 persons each of whom is a medical practitioner eminent in his or her profession and of whom at least 3 are specialists in clinical medicine; and

(b) not less than 2 persons, each of whom is a pharmacologist or a person who has been admitted to a degree in science or a branch of science by a university and has specialised in pharmaceutical science.

(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.

Minister or Secretary may seek further advice

37. Where a Committee established under this Part 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 Part and that other Committee may make comments to the Minister or the Secretary in relation to that advice as it thinks fit.

Tenure of office of members

38. (1) A member of a Committee established under this Part holds office for not more than 3 years unless the member is removed from office before the end of that period.

(2) A member is eligible for re-appointment.

(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.

Disclosure of interests

39. (1) A member of a Committee established under this Part 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.

Acting members

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

(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.

Meetings of Committees

41. (1) Meetings of a Committee established under this Part 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—4 members constitute a quorum: and

(c) in the case of the Therapeutic Device Evaluation Committee—4 members constitute a quorum.

(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.

Effect of vacancy on Committees

42. The exercise of a power or the performance of a function of a Committee established under this Part is not affected by a vacancy or vacancies in the membership of that Committee.

PART 7—FEES AND COSTS

Fees

43. (1) The fees specified in column 3 of an item in Schedule 9 are prescribed in respect of the matters specified in column 2 of that 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.

(3) A reference in Schedule 9 to a page, is a reference:

(a) to a legible photocopy:

(i) of a single side of a single leaf of a published work; or

(ii) of a diagram or chart; or

(b) to a single side of a single leaf of any other work that:

(i) is 297 millimetres in length and 210 millimetres wide; and

(ii) is typed or printed in legible characters that is not less than 8 points in size; and

(iii) has a left hand margin that is not less than 25 millimetres wide; and

(iv) if the leaf is from a document that exceeds 1 page in length—is paginated.

Testing of samples—recovery of costs

44. 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.

Waiver or reduction of fees

45. (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 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 the evaluation fees specified in Schedule 9 payable in relation to therapeutic goods if a person submits more than one application for registration of the goods at the same time and:

(a) the goods in each application contain the same therapeutically active ingredient: and

(b) the information submitted in support of each application is sufficiently common in respect of the goods to enable a simultaneous evaluation of the goods to be made.

(3) The Secretary may waive or reduce the application and evaluation fees specified in Schedule 9 payable in relation to the entry of therapeutic goods in the Register 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.

PART 8—MISCELLANEOUS

Release of information

46. (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 the goods are included. the registration or listing number of the goods. the date on which the goods were listed or registered and the class in which the goods are included:

(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 drugs, therapeutic devices that contain drugs or therapeutic devices that are presented in a pharmaceutical form:

(i) the quantity of goods to be in the primary pack; and

(ii) the entry relating to the goods in the Poisons Schedule; 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 therapeutic devices, a description of the devices, including the name and code (if any) by which the devices are classified.

Delegation

47. The Secretary may, by signed instrument, delegate to an officer of the Department all or any of the Secretary's powers and functions under these Regulations other than the power of delegation.

Review of decisions

48. (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 regulation 7 or 9, subregulation 13 (7) or 22 (8) or regulation 45;

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

(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

Subregulation 4 (2)

PART 2 DOES NOT APPLY TO MEMBERS OF AN AUSTRALIAN BRANCH OF ONE OF THESE BODIES

Column 1 Item No.	Column 2 Body
1	Acupuncture Association of Australia
2	Acupuncture Ethics and Standards Organisation
3	Association of Natural Health Practitioners
4	Australasian Federation of Natural Therapy Associations Inc.
5	Australian Acupuncture Association Inc.
6	Australian Association of Professional Homoeopaths
7	Australian Committee of Natural Therapies Inc. (SA)
8	Australian Council of Natural Therapies Inc.
9	Australian Federation of Homoeopaths
10	Australian Natural Therapists Association Ltd
11	Australian Naturopathic Practitioners and Chiropractors Association
12	Australian Traditional Chinese Herbalists Association (Qld)
13	Australian Traditional Chinese Medicine Association Inc.
14	Australian Traditional Medicine Society
15	Chinese Medicine Association Pty Ltd
16	Complementary Medicine Association
17	Homoeopathic Education and Research Association
18	National Herbalists Association of Australia
19	Queensland Naturopathic Association
20	Register of Acupuncture and Traditional Chinese Medicine
21	Society of Natural Therapists and Researchers Inc.
22	Society of Classical Homoeopathy Ltd
23	Traditional Medicine of China Society Australia

SCHEDULE 2

Regulation 8

PROHIBITED AND REQUIRED REPRESENTATIONS FOR THE PURPOSES OF PARAGRAPHS 6 (1) (a) AND (b)

PART 1

PROHIBITED REPRESENTATIONS

Column 1 Item No.	Column 2 Representation	Column 3 Therapeutic goods
1	a representation referred to in clause 4 of the Therapeutic Goods Advertising Code	all therapeutic goods
2	a representation referred to in Clause 7 of 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	all therapeutic goods

SCHEDULE 2—continued

Column 1 Item No.	Column 2 Representation	Column 3 Therapeutic goods
	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	
4	a representation referred to in clause 5.3 of the Therapeutic Goods Advertising Code	analgesics
5	a representation containing a reference to bacteriostatic activity, except where it is made in conjunction with a reference to bactericidal activity	disinfectants
6	a representation: (a) containing reference to the Rideal-Walker test or to 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	disinfectants and antiseptics
7	a representation that antiseptics promote healing	antiseptics
8	a representation referred to in clause 6.1 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

SCHEDULE 2—continued

PART 2

REQUIRED REPRESENTATIONS

Column 1 Item No.	Column 2 Representation	Column 3 Therapeutic goods
1	a statement that vitamins can only be of assistance if the dietary vitamin intake is inadequate	vitamin preparations supplied in Australia

PART 3

VITAMINS REFERRED TO IN ITEM 3 OF PART 1 OF THIS SCHEDULE

Column 1 Item No.	Column 2 Substance	Column 3 Name
1	Vitamin A	—
2	Thiamine	Vitamin B1
3	Riboflavine	Vitamin B2
4	Nicotinic Acid	Vitamin B3
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

Regulation 10

THERAPEUTIC GOODS REQUIRED TO BE INCLUDED IN THE PART OF THE REGISTER FOR REGISTERED GOODS

Item No.	Therapeutic goods
1	drugs other than drugs referred to in item 1 in Part 1 of Schedule 4
2	drugs, other than drugs: (a) referred to in items 3 to 10 (inclusive) in Part 1 of Schedule 4; or (b) referred to in item 1, 2, 3, 4, 5, 6, 8, 9, 10 or 11 in Schedule 5; unless those drugs are supplied as pharmaceutical benefits
3	therapeutic devices that are: (a) implantable intra-ocular lenses; or (b) intra-uterine contraceptive devices; or (c) implantable cardiac pacing systems, including pulse generators, defibrillators, cardioverters, antitachycardia devices and their accessories; or (d) prosthetic heart valves; or (e) intra-ocular visco-elastic fluids; or (f) powered drug infusion systems which regulate the flow of infusate; or (g) devices of human or animal origin (other than de-natured coral) for use on or in the body of a person

SCHEDULE 4

Regulation 11

THERAPEUTIC GOODS REQUIRED TO BE INCLUDED IN THE PART OF THE REGISTER FOR LISTED GOODS

PART 1

LISTABLE THERAPEUTIC 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 of Schedule 3 applies; or (b) item 1, 2, 3, 4, 5, 6 or 7 of Schedule 5 applies
3	preparations containing as their therapeutically active ingredients only vitamins, minerals, herbal substances or other substances specified in Part 5 of this Schedule or a combination of those substances where: (a) the preparation is not included in a Schedule to the Poisons Standard or 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 herbal substances are not derived from herbs specified in Part 4 of this Schedule; unless the indications proposed by the sponsor of the preparation are in the treatment of a condition referred to in clause 4 of the Therapeutic Goods Advertising Code
4	mother tinctures and homoeopathic preparations where each dilution of a mother tincture does not exceed a one thousand fold dilution, each of which: (a) is not required to be sterile; and (b) is not subject to a Schedule to the Poisons Standard
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 condition which is referred to in clause 4 of the Therapeutic Goods Advertising Code

SCHEDULE 4—continued

Item No.	Therapeutic goods
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 condition referred to in clause 4 of the Therapeutic Goods Advertising Code
7	sunscreen preparations for dermal use that, when tested as described in Australian Standard AS2604-1986 as amended and in force from time to time, are established to have, and claim on their labels, a sun protection factor of 4 or greater (or the equivalent category description) unless the indications proposed by the sponsor of the preparation are in the treatment of a condition referred to in clause 4 of the Therapeutic Goods Advertising Code
8	uncompounded drug 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 condition referred to in clause 4 of the Therapeutic Goods Advertising Code
9	medicated space sprays where the medication consists only of volatile oils and their constituents
10	drugs containing amino acids for therapeutic use singly or in combination with other substances unless: (a) the amino acids are tryptophan, arginine, d or dl phenylalanine, methionine, carnitine or glutamic acid and its salts; 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 condition referred to in clause 4 of the Therapeutic Goods Advertising Code

SCHEDULE 4—continued

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	
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	
Nicotinic acid	
Panthenol	
Pantothenic acid	Vitamin B5
Phytomenadione	Vitamin K1
Potassium ascorbate	
Pyridoxine hydrochloride	Vitamin B6
Retinyl acetate	Vitamin A acetate
Retinyl palmitate	Vitamin A palmitate
Riboflavine	Vitamin B2
Riboflavine sodium phosphate	
Sodium ascorbate	
Sodium pantothenate	
Thiamine hydrochloride	Vitamin B1
Thiamine nitrate	
d-alpha-Tocopherol	Vitamin E
dl-alpha-Tocopherol	
d-alpha-Tocopheryl acetate	
dl-alpha-Tocopheryl acetate	
d-alpha-Tocopheryl acid succinate	
dl-alpha-Tocopheryl acid succinate	
Vitamin A	Retinol

SCHEDULE 4—continued

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
Calcium amino acid chelate as a source of calcium
Calcium carbonate
Calcium citrate
Calcium gluconate
Calcium glycerophosphate
Calcium hydrogen phosphate
Calcium lactate
Calcium orotate
Calcium phosphate
Calcium sodium lactate
Calcium succinate
Calcium sulfate
Chromium (III) chloride
Copper gluconate
Copper (II) oxide
Copper (II) sulfate
Ferric glycerophosphate
Ferric pyrophosphate
Ferrous carbonate
Ferrous chloride
Ferrous fumarate
Ferrous gluconate
Ferrous phosphate
Ferrous succinate
Ferrous sulfate
Iron amino acid chelate as a source of iron
Iron (III) chloride
Magnesium amino acid chelate as a source of magnesium
Magnesium aspartate
Magnesium carbonate
Magnesium chloride
Magnesium citrate
Magnesium gluconate
Magnesium glycerophosphate
Magnesium orotate
Magnesium oxide
Magnesium phosphate
Magnesium sulfate
Manganese aspartate
Manganese chloride
Manganese gluconate
Manganese glycerophosphate
Manganese (IV) oxide
Manganese (II) sulfate
Potassium aspartate
Potassium citrate
Potassium gluconate
Potassium glycerophosphate

SCHEDULE 4—continued

Name
Potassium iodide
Potassium orotate
Potassium phosphate
Potassium sulfate
Sodium chloride
Sodium glycerophosphate
Sodium phosphate
Zinc amino acid chelate as a source of zinc
Zinc chloride
Zinc citrate
Zinc gluconate
Zinc oxide
Zinc succinate
Zinc sulfate

PART 4

HERBS TO WHICH PARAGRAPH (d) OF ITEM 3 OF PART 1 OF THIS SCHEDULE APPLIES

Name	Common Name
Abrus precatorius	Jequirity
Acorus calamus	Sweet flag, Blue flag
Argyreia nervosa	Morning glory
Aristolochia species	Snakeroot, Birthwort
Amanita muscaria & spp.	
Anadenanthera peregrina	
Banisteriopsis caapi	Banisteria
Brachyglottis species	
Cannabis	
Catha edulis	Khat
Conocybe siligineoides and species	
Crotolaria species	
Cynoglossum officinale	Hounds tongue
Echium vulgare	Viper's bugloss
Erythroxylum coca	Coca leaf
Gymnopilus species	
Haemadictyon species	
Heliotropium species	Heliotrope
Ipomoea burmanni	Rivea corymbosa
Ipomoea hederacea	
Ipomoea tricolor	
Ipomoea violacea	
Lithospermum species	
Lophophora species	
Opuntia cylindrica	San Pedro cactus
Papaver bracteatum	
Papaver somniferum	Opium poppy
Peganum harmala	Wild rue
Petasites species	Butterbur
Phytolacca decandra (americana)	Pokeweed
Piptadenia macrocarpa	

SCHEDULE 4—continued

Name	Common Name
Piptadenia peregrina	Cohoba
Psylocybe species	
Pteridium aquilinum	Bracken Fern
Sassafras albidum	Sassafras
Senecio species	Liferoot
Solanum dulcamara	Bittersweet
Sophora secundiflora	Mescal bean
Stropharia cubensis	
Strychnos gautheriana	
Strychnos ignatii	Ignatious bean
Symphytum species	Comfrey
Tussilago farfara	Coltsfoot

PART 5

SUBSTANCES TO WHICH ITEM 3 OF PART 1 OF THIS SCHEDULE APPLIES

Name
Bioflavonoids (other than quercetin)
Choline bitartrate
Chlorophyll
Dolomite
Fish oils used as a source of omega—3 marine triglycerides where the recommended daily intake of omega—3 marine triglycerides is less than 1 gram
Fructose
Glucose
Inositol
Lecithin
Methylcellulose
Oyster shell
Pectin

SCHEDULE 5

Regulation 12

THERAPEUTIC GOODS EXEMPT FROM THE OPERATION OF PART 3 OF THE ACT

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—the goods are the subject of an approval under section 19 of the Act; and (c) in the case of other drugs—the quantity imported represents not more than 3 month's supply at the maximum dose recommended by the manufacturer; and (d) if the goods are subject to Schedule 4 to the Poisons Standard—the goods are the subject of a written authority issued by a medical practitioner registered under a law of a State or Territory, except where the goods are carried by the importer as a passenger on a ship or aeroplane
2	therapeutic goods that are exported and that: (a) are not for commercial supply; and (b) do not contain a substance the exportation of which is prohibited under the *Customs Act 1901*
3	samples of therapeutic goods 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	goods imported into Australia that are held under the direct control of the sponsor pending approval for registration or listing

SCHEDULE 5—continued

Column 1 Item No.	Column 2 Therapeutic goods
6	therapeutic goods that are produced or dispensed or extemporaneously compounded for a particular person for therapeutic application to that person (other than therapeutic devices referred to in item 3 of Schedule 3, or electronic devices that must be programmed for each patient using them)
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; (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 (iv) goods for use in the diagnosis of infection with Human Immunodeficiency Virus; or (v) antimicrobic susceptibility discs (c) non implantable, non powered diagnostic tools and instruments that are not supplied in a sterile state and that are not referred to in paragraph (b); (d) non-powered surgical or dental instruments that depend on manual dexterity for their use and are not supplied in a sterile state, other than flexible tubes, catheters, cannulae, fluid and gas lines and other instruments that introduce fluids or gases to, or remove them from, the body; (e) manufacturing, laboratory and dispensary equipment used in the preparation of therapeutic goods other than equipment specifically designed to process a patient's blood or other tissues for reintroduction to that patient;

SCHEDULE 5—continued

Column 1 Item No.	Column 2 Therapeutic goods
	(f) therapeutic devices for dental use (other than devices of human or animal origin and devices that, when used, are implanted directly into bone or soft tissue) that are: (i) constructed externally to the mouth and fitted or fixed into the mouth on a temporary or permanent basis and intended to correct an irregularity or deficiency; or (ii) dental impression materials; including devices worn to protect teeth from external trauma; (g) non-powered equipment used in general patient care being equipment that does not constitute or contribute to a specific diagnosis, monitoring or treatment of a medical condition; (h) furniture other than powered appliances for use in diagnosis or treatment of a medical condition; (i) linen and bedding other than linen and bedding supplied in a sterile state; (j) protective clothing for patients or health workers other than: (i) clothing supplied in a sterile state; or (ii) surgeon's gloves and patient examination gloves; or (iii) patient nuclear radiation shielding apparel; (k) communications equipment; (l) containers other than syringes (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
8	the following drugs unless the indications proposed by the sponsor are in the treatment of a condition referred to in clause 4 of 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; (b) antiperspirant preparations that derive their antiperspirant properties from inorganic salts of aluminium, zinc or zirconium only;

SCHEDULE 5—continued

Column 1 Item No.	Column 2 Therapeutic goods
	(c) unmedicated anti-acne preparations having only a cleansing action or purpose; (d) medicated insect repellants for dermal use except those that are included in a Schedule to the Poisons Standard; (e) lotions, shampoos or hairdressings for the prevention or treatment of dandruff except those that are included in a Schedule to the Poisons Standard; (f) disinfectants; (g) sunscreen preparations for dermal use that when tested as described in Australian Standard AS2604-1986 as amended from time to time, are established to have, and claim on their labels, a sun protection factor below 4 or the equivalent category description
9	the following drugs: (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 Australian Red Cross Society
10	Japanese encephalitis vaccine: (a) that is imported by the undertaking known as Commonwealth Serum Laboratories for supply to Fairfield Hospital in the State of Victoria; and (b) that is supplied to that Hospital for use in patients who have given adequately informed consent to the proposed treatment before it is commenced, being patients who: (i) are to be resident for more than 12 months in an area in which Japanese encephalitis is endemic; or (ii) make, or are to make, repeated short trips to areas in which Japanese encephalitis is endemic; or (iii) intend to visit rural areas in areas in which there is an epidemic of Japanese encephalitis; and (c) that is to be approved for administration to each patient by, or at the direction of, the Director of Medical Services at that Hospital; and

SCHEDULE 5—continued

Column 1 Item No.	Column 2 Therapeutic goods
	(d) that is prescribed by a medical practitioner working at the hospital who is not the person who approved its administration to the patient to whom it is administered
11	therapeutic goods: (a) in relation to the importation of which a licence or permission is in force: (i) under regulation 5A, 5B or 5C of the Customs (Prohibited Imports) Regulations; and (ii) by the Secretary or, in the case of a licence or permission granted under regulation 5A, 5B or 5C of those Regulations, by an authorised person within the meaning of that regulation; and (iii) before the commencement of the Act; and (b) which are supplied in Australia for use in humans not more than 6 months after the commencement of the Act

SCHEDULE 6

Regulation 16

THERAPEUTIC DEVICES PRESCRIBED FOR THE PURPOSES OF PARAGRAPH 26 (1) (g) OF THE ACT

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) materials for the restoration or replacement of teeth or other devices intended to be implanted in the human body; or (c) bandages, dressings, absorbents, adhesive tapes and similar products (other than casting materials) used in the treatment of wounds, burns or lesions or in surgical procedures; 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 (iii) goods for use in the diagnosis of infection with Human Immunodeficiency Virus; or (iv) antimicrobic susceptibility discs
4	containers (not being glass containers) that are: (i) designed to contain blood or blood components; or (ii) intended for use with goods for parenteral administration

SCHEDULE 7

Regulation 17

THERAPEUTIC GOODS EXEMPT FROM THE OPERATION OF PART 4 OF THE ACT UNLESS SUPPLIED AS PHARMACEUTICAL BENEFITS

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, 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 except where the devices are intended to be inserted into the human body (other than devices exempt from the operation of Part 3 of the Act) and those components come into direct contact with body tissue or body fluids
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) materials for restoration or replacement of teeth or other devices intended to be implanted in the human body; or (c) bandages (excluding casting bandages), dressings, gauzes and undercast padding; 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 (iii) goods for use in the diagnosis of infection with Human Immunodeficiency Virus; or (iv) antimicrobic susceptibility discs
5	containers (other than glass containers) that are not:

3941

SCHEDULE 7—continued

Column 1 Item No.	Column 2 Therapeutic goods
	(a) designed to contain blood or blood components (other than containers used to collect blood for subsequent diagnostic testing); or (b) intended for use with goods for parenteral administration
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
11	lotions, shampoos or hairdressings for the prevention or treatment of dandruff
12	medicated soaps other than liquid medicated soaps
13	disinfectants
14	sunscreen preparations for dermal use
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

SCHEDULE 8

Regulation 18

PERSONS EXEMPT FROM THE OPERATION OF PART 4 OF THE ACT

Column 1 Item No.	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 drug 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
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 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

3941

SCHEDULE 8—continued

Column 1 Item No.	Column 2 Persons	Column 3 Matter in relation to which person exempted
6	persons who operate blood collection centres	the operation of human blood collection centres except those that supply plasma for the manufacture of blood components

SCHEDULE 9

Regulation 43

FEES

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
1	evaluation fee for the purposes of subparagraph 19 (2) (b) (iii) of the Act:	
	(a) if the goods are drugs for use solely for experimental purposes in humans and the evaluation is based only on a check list of chemistry and quality control information and guidelines relating to clinical usage	800
	(b) if the goods are drugs for use solely for experimental purposes in humans (other than drugs to which paragraph (a) applies)—for each drug	10,100
	(c) if the goods are therapeutic devices referred to in item 3 of Schedule 3 for use solely for experimental purposes in humans where clinical studies are conducted to demonstrate safety and effectiveness	7,000
	(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	800
2	application fee for the purposes of paragraph 23 (c) of the Act for registration of therapeutic goods:	
	(a) if the application is an application to which item 5 applies	300
	(b) if the application is an application to which item 4 (c) (i) applies	nil
	(c) subject to paragraph (d), in any other case	1,000
	(d) if a person submits more than one application at the same time and:	500
	(i) the additional application is in relation to goods that contain the same therapeutically active ingredient(s); and	

394

SCHEDULE 9—continued

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
	(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:	
	then for each additional application	
3	application fee for the purposes of paragraph 23 (c) of the Act for listing of therapeutic goods	60
4	evaluation fee for the purposes of subsection 24 (1) of the Act in respect of therapeutic goods evaluated by the Drug Evaluation Branch of the Department involving the evaluation of:	
	(a) human clinical information comprising:	
	(i) not more than 200 pages	8,000
	(ii) more than 200 pages but not more than 2,000 pages	18,000
	(iii) more than 2,000 pages	35, 000
	(b) animal toxicological information comprising:	
	(i) not more than 200 pages	5,000
	(ii) more than 200 pages	18,000
	(c) chemistry, quality control and manufacturing information comprising:	
	(i) not more than 50 pages	2,900
	(ii) more than 50 pages	6,400
5	evaluation fee for the purposes of subsection 24 (1) of the Act in respect of a drug to which item 4 does not apply	1,700
6	evaluation fee for the purposes of subsection 24 (1) of the Act in respect of a therapeutic device involving the evaluation of:	
	(a) design or materials information or testing undertaken by the Department:	7,000
	(b) manufacture, quality control or sterile manufacture or testing information:	4,000
	(c) biocompatability or pre-clinical information:	4,000
	(d) human clinical information	8,000
7	evaluation fee for data submitted in support of a change to a registered device where the evaluation involves review of:	
	(a) design or materials information or testing undertaken by the Department:	2,300
	(b) manufacturing, quality control and sterile manufacture or testing information:	1,300
	(c) biocompatability or pre-clinical information:	2,000
	(d) human clinical information	8,000
8	application fee for the purposes of paragraph 37 (1) (g) of the Act	300

3941

SCHEDULE 9—continued

Column 1 Item	Column 2 Matter	Column 3 Fee
		$
9	inspection fee for the purposes of paragraph 38 (1) (c), 41 (1) (f) or 58 (3) (b) of the Act:	
	(a) if the fee is in relation to the manufacture of a single type of therapeutic device that is, or is represented, to be sterile:	
	(i) initial half day of inspection	2,400
	(ii) each additional half day	1,400
	(b) if the fee is in relation to the manufacture of therapeutic goods to which paragraph (a) does not apply that are, or are represented, to be sterile:	
	(i) initial half day of inspection	2,400
	(ii) each additional half day	1,400
	(c) if the fee is in relation to the manufacture of therapeutic goods that are not sterile:	
	(i) initial half day of inspection	2,400
	(ii) each additional half day	1,400
	(d) if the fee is in relation to a single step in the manufacture of therapeutic goods:	
	(i) initial half day of inspection	1,200
	(ii) each additional half day	800
	(e) if the fee is in relation to the manufacture of ingredients or components for use in the manufacture of therapeutic goods and paragraph (d) does not apply:	
	(i) initial half day of inspection	1,200
	(ii) each additional half day	800
	(f) if the fee is in relation to the manufacture of herbal or homoeopathic preparations and the preparations are not included in a schedule of the Poisons Standard:	
	(i) initial half day of inspection	1,200
	(ii) each additional half day	800
10	fee for the issue to a person of a certification under paragraph 58 (3) (a) of the Act	50
11	fee for the inspection of manufacturing operations other than for the purposes of Part 4 of the Act	The fee applicable under item 9 for that step of manufacture
12	fee for an evaluation of data concerning therapeutic goods by the Department other than for the purposes of Part 3 of the Act or for the evaluation of data to support a modification to a registered or listed drug	The fee applicable under item 1, 4, 5, 6 or 7 for an evaluation of that nature

SCHEDULE 9—continued

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

NOTE

1. Notified in the *Commonwealth of Australia Gazette* on 4 1990.

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