Western Australia

Therapeutic Goods (Western Australia) Bill 2000

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Defined Terms

Western Australia

LEGISLATIVE ASSEMBLY

Therapeutic Goods (Western Australia) Bill 2000

A Bill for

An Act to promote and facilitate the development of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods, and for that purpose to make provision in Western Australia for the implementation of controls forming part of such a system complementary, and additional, to the provision made by the *Therapeutic Goods Act 1989* of the Commonwealth and, as a consequence, to repeal or amend various written laws.

The Parliament of Western Australia enacts as follows:

Part 1 — Preliminary

1. Short title

This Act may be cited as the *Therapeutic Goods (Western Australia) Act 2000.*

2. Commencement

This Act comes into operation on a day fixed by proclamation.

3. Objects of Act (Cwlth s. 4)

The objects of this Act are —

(a) to promote and facilitate the development of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods;

(b) to make provision in Western Australia for the implementation of controls forming part of such a system complementary, and additional, to the provision made by the Commonwealth Act.

4. Interpretation (Cwlth s. 3)

(1) In this Act —

"advertisement", in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods;

"annual licensing charge" means an amount equal to the amount of the charge payable by the holder of the licence to which the charge relates under Part 5 of the Commonwealth Act;

"annual listing charge" means an amount equal to the amount of the charge payable by a person in relation to whom

therapeutic goods are listed under Part 5 of the Commonwealth Act;

"annual registration charge" means an amount equal to the amount of the charge payable by a person in relation to whom therapeutic goods are registered under Part 5 of the Commonwealth Act;

"authorised person" means —

(a) in relation to any provision of this Act, a person authorised under section 7(1) or (2) to exercise powers under that provision; or

(b) in relation to a provision of Part 7—

(i) a member of the Police Force of Western Australia; or

(ii) a member of the Australian Federal Police;

"automatic machine" means a machine or mechanical device used or capable of being used for the purposes of selling or supplying goods without the personal manipulation or attention of the seller or supplier, or an agent or employee of the seller or supplier at the time of that sale or supply;

"Commissioner" has the same meaning as it has for the purposes of the *Health Act 1911*;

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

"Commonwealth Department" means the Department of Health and Aged Care or such other Department of the Commonwealth as is the relevant Department for the purposes of the Commonwealth Act;

"Commonwealth Minister" means the Minister administering the Commonwealth Act;

"Commonwealth regulations" means the regulations for the time being in force under the Commonwealth Act;

"exempt goods" means —

(a) in relation to a provision of Part 3, therapeutic goods that are exempt from the operation of Part 3 of the Commonwealth Act;

(b) in relation to a provision of Part 4, therapeutic goods that are exempt from the operation of Part 4 of the Commonwealth Act; and

(c) in relation to any provision of this Act, therapeutic goods that are exempt for the purposes of that provision because of an order under section 9 where the goods are used, advertised or presented for supply in the way specified in the order;

"exempt person" means —

(a) in relation to therapeutic goods, a person exempt from the operation of Part 4 of the Commonwealth Act in relation to those goods; or

(b) in relation to any provision of this Act, a person exempt from that provision because of an order under section 9;

"gazetted kits group" means a group of kits identified in an order made under section 16(3A) of the Commonwealth Act or section 14(4) of this Act;

"gazetted therapeutic devices group" means a group of therapeutic devices identified in an order made under section 16(3) of the Commonwealth Act or section 14(3) of this Act;

"gazetted therapeutic goods group" means a group of therapeutic goods identified in an order made under section 16(2) of the Commonwealth Act or section 14(2) of this Act;

"grouped therapeutic goods" means therapeutic goods included in —

(a) a gazetted therapeutic goods group;

(b) a gazetted therapeutic devices group; or

(c) a gazetted kits group;

"licence" means a licence under Part 4;

"listable devices" means therapeutic devices that are required under this Act or the Commonwealth Act to be included in the part of the Register for listed goods;

"listed goods" means therapeutic goods that are included in the part of the Register for goods known as listed goods;

"listing number", in relation to listed goods, means any combination of numbers, symbols and letters assigned to the goods under section 27 of the Commonwealth Act or section 36 of this Act;

"protected information" has the meaning given in section 31(2);

"Register" means the Australian Register of Therapeutic Goods maintained under section 17 of the Commonwealth Act;

"registered goods" means therapeutic goods that are included in the part of the Register for goods known as registered goods;

"registration number", in relation to registered goods, means any combination of numbers, symbols and letters assigned to the goods under section 27 of the Commonwealth Act or section 36 of this Act;

"Secretary" means the Secretary to the Commonwealth Department;

"sponsor", in relation to therapeutic goods, means a person who, in Western Australia, manufactures the goods, or arranges for another person to manufacture the goods, for

supply (whether in Western Australia or elsewhere) but does not include a person who —

(a) manufactures the goods; or

(b) arranges the manufacture of the goods,

on behalf of another person who, at the time of the manufacture or arrangements, is a resident of, or is carrying on business in, Western Australia;

"standard", in relation to therapeutic goods, means a standard that —

(a) is specified in an order under section 10 of the Commonwealth Act that is applicable to the goods in accordance with section 13 of that Act; or

(b) if no such order is so applicable to the goods but the goods are the subject of a monograph in —

(i) in the case of goods for use in humans, the British Pharmacopoeia; or

(ii) in the case of goods for use in animals, the British Pharmacopoeia (Veterinary),

is constituted by the statements in that monograph;

"supply" includes —

(a) supply by way of sale, exchange, gift, lease, loan, hire or hire-purchase;

(b) supply, whether free of charge or otherwise, by way of sample or advertisement;

(c) supply, whether free of charge or otherwise, in the course of testing the safety or efficacy of therapeutic goods in persons or animals; and

(d) supply by way of administration to, or application in the treatment of, a person or animal;

"therapeutic device" means therapeutic goods consisting of an instrument, apparatus, appliance, material or other article (whether for use alone or in combination), together with any accessories or software required for its proper functioning, which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means though it may be assisted in its function by such means, but the expression does not include therapeutic goods declared under the Commonwealth Act not to be therapeutic devices;

"therapeutic goods" means goods —

(a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be —

(i) for therapeutic use;

(ii) for use as an ingredient or component in the manufacture of therapeutic goods; or

(iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or

(b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in paragraph (a)(ii) or (iii),

and includes goods declared to be therapeutic goods under an order in force under section 7 of the Commonwealth Act, but does not include —

(c) goods declared not to be therapeutic goods under an order in force under that section or under an order under section 9 of this Act;

(d) goods in respect of which such an order is in force, being an order that declares the goods not to be

therapeutic goods when used, advertised or presented for supply in the way specified in the order where the goods are used, advertised or presented for supply in that way;

(e) goods for which there is a prescribed standard in the Australian New Zealand Food Standards Code as defined in section 3(1) of the *Australia New Zealand Food Authority Act 1991* of the Commonwealth; or

(f) goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented;

"therapeutic use" means use in or in connection with —

(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals;

(b) influencing, inhibiting or modifying a physiological process in persons or animals;

(c) testing the susceptibility of persons or animals to a disease or ailment;

(d) influencing, controlling or preventing conception in persons;

(e) testing for pregnancy in persons; or

(f) the replacement or modification of parts of the anatomy in persons or animals.

(2) For the purposes of this Act —

(a) therapeutic goods are to be taken to be for use in animals if —

(i) the goods bear a name or description that indicates, or is likely to give the impression, that the goods are intended for use in animals and are not intended for use in humans; or

(ii) the goods are otherwise represented, or otherwise purport, to be intended for use in animals and not intended for use in humans;

and

(b) therapeutic goods are to be taken to be for use in humans if they are not solely for use in animals.

(3) For the purposes of this Act, the presentation of therapeutic goods is unacceptable if it is capable of being misleading or confusing as to the content or proper use of the goods and, without limiting the previous words in this subsection, the presentation of therapeutic goods is unacceptable —

(a) if it states or suggests that the goods have ingredients, components or characteristics that they do not have;

(b) if a name applied to the goods is the same as the name applied to other therapeutic goods that are supplied in Western Australia where those other goods contain additional or different therapeutically active ingredients;

(c) if the label of the goods does not declare the presence of a therapeutically active ingredient;

(d) if a form of presentation of the goods may lead to unsafe use of the goods or suggests a purpose that is not in accordance with conditions applicable to the supply of the goods in Western Australia; or

(e) in prescribed cases.

(4) A word or expression used in this Act has the same meaning as in the Commonwealth Act unless —

(a) this Act gives it another meaning; or

(b) the contrary intention appears in some other way.

(5) Notes in this Act are provided to assist understanding and do not form part of this Act.

5. Act to bind Crown (Cwlth s. 5)

(1) This Act binds the Crown in right of Western Australia and, so far as the legislative power of Parliament permits, the Crown in all its other capacities.

(2) Nothing in this Act renders the Crown in any of its capacities liable to be prosecuted for an offence.

6. This Act in addition to other written laws relating to therapeutic goods

If another written law relates to therapeutic goods that law applies in addition to this Act, unless a written law expressly provides otherwise.

7. Authorised persons (Cwlth s. 7A)

(1) The Commissioner may, in writing, authorise any person to exercise powers under a specified provision of this Act.

(2) A person who is an authorised person under the Commonwealth Act in respect of a provision of that Act is authorised to exercise powers under the corresponding provision of this Act.

(3) In subsection (2) —

"corresponding provision" in relation to a section of the Commonwealth Act referred to in the heading to a section of this Act, means that section of this Act, unless otherwise prescribed.

8. Secretary may approve or authorise the supply of certain therapeutic goods (Cwlth s. 19)

(1) The Secretary may, by notice in writing, grant an approval to a person to supply specified therapeutic goods that are not either exempt goods or goods included in the Register —

(a) for use in the treatment of another person; or

(b) for use solely for experimental purposes in humans.

(2) An approval under subsection (1) —

(a) is subject to the conditions specified in the approval; and

(b) may include a condition relating to the charges that may be made for the supply of the therapeutic goods to which the approval relates.

(3) An application for an approval must be made to the Secretary and —

(a) in the case of an application for use of the kind referred to in subsection (1)(a), must be accompanied by such information relating to the goods that the Secretary requires; and

(b) in the case of an application for use of the kind referred to in subsection (1)(b) —

(i) must be made in writing;

(ii) must be accompanied by such information relating to the goods that the Secretary requires; and

(iii) must be accompanied by a fee which is an amount equal to the evaluation fee prescribed for the purposes of section 19(2)(b)(iii) of the Commonwealth Act.

(4) If an application for an approval is made, the Secretary must notify the applicant of his or her decision on the application within 28 days of making the decision and, in the case of a decision not to grant the approval, of the reasons for the decision.

(5) The Secretary may, in writing, authorise an approved medical practitioner to supply —

(a) specified therapeutic goods for use in the treatment of humans; or

(b) a specified class of such goods,

to the class or classes of recipients specified in the authority, being a class or classes of recipients to whom therapeutic goods of that kind may be supplied in accordance with an authority under section 19(5) of the Commonwealth Act.

(6) An authority given under subsection (5) may authorise supply in the same circumstances as the circumstances in which the holder of an authority under section 19(5) of the Commonwealth Act may supply therapeutic goods.

(7) In this section —

"approved medical practitioner" means a medical practitioner registered under the *Medical Act 1894* of a class eligible to be given an authority under section 19(5) of the Commonwealth Act.

(8) The giving of an approval under subsection (1) or an authority under subsection (5) does not render the Commonwealth, the State, the Secretary or a delegate of the Secretary liable to a person in respect of loss, damage or injury of any kind suffered by a person as a result of, or arising out of, the use of therapeutic goods by that person or another person.

9. Power of Minister to exempt

(1) The Minister may, by order published in the *Gazette* —

(a) exempt —

(i) any person or class of persons; or

(ii) any goods or class of goods,

specified in the order from all provisions of this Act, or from such provisions of this Act as are specified in the order; or

(b) declare that goods are exempt goods for the purposes of a provision of this Act when those goods are used, advertised or presented for supply in the way specified in the order.

(2) An order under this section is subject to such conditions, if any, as are specified in the order.

10. Kits (Cwlth s. 7B)

(1) A package and therapeutic goods in the package together constitute a kit for the purposes of this Act if —

(a) the package and the therapeutic goods are for use as a unit;

(b) each item of the therapeutic goods consists of goods that are registered or listed or are therapeutic goods that are exempt from the operation of Part 3 of the Commonwealth Act; and

(c) the package and therapeutic goods do not constitute a composite pack.

(2) A package and therapeutic goods in the package together constitute a composite pack if —

(a) the therapeutic goods are of 2 or more kinds;

(b) the package does not contain any therapeutic devices;

(c) the therapeutic goods are for administration as a single treatment or as a single course of treatment; and

(d) it is necessary that the therapeutic goods be combined before administration or that they be administered in a particular sequence.

(3) To avoid doubt, it is declared that a kit constitutes therapeutic goods.

11. Power to obtain information with respect to therapeutic goods (Cwlth s. 8)

(1) The Secretary may, by notice in writing given to a person who has supplied in Western Australia —

(a) therapeutic goods; or

(b) goods in relation to which the Secretary is considering making a declaration under section 7 of the Commonwealth Act,

request the person to give to an officer of the Commonwealth Department identified in the notice, within such reasonable period as is specified in the notice, information required by the notice concerning the composition, indications, directions for use or labelling of the goods or concerning advertising material relating to the goods.

(2) A notice under subsection (1) may require the information to be given —

(a) in writing; or

(b) in accordance with specified software requirements —

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

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

(3) A person must not, without reasonable excuse, fail to comply with a notice given to the person under subsection (1).

(4) A person must not, in purported compliance with a notice under subsection (1), make a statement that is false or misleading in a material particular if the person knows, or ought reasonably to

know, that the statement is false or misleading in a material particular.

Penalty: $10 000.

Part 2 — Standards

12. Compliance with standards (Cwlth s. 14)

(1) Except with the consent in writing of the Secretary under this section or section 14 of the Commonwealth Act, a person must not supply therapeutic goods for use in Western Australia if the goods do not conform with a standard applicable to the goods.

Penalty: $25 000.

(2) The Secretary must, as soon as practicable after making a decision to give a consent under this section, cause particulars of the decision to be published in the Commonwealth of Australia Gazette.

(3) The Secretary must, within 28 days after making a decision to refuse to give a consent under this section, notify the applicant in writing of the decision and of the reasons for the decision.

13. Consent may be subject to conditions etc. (Cwlth s. 15)

(1) The consent of the Secretary under section 12 may be given —

(a) unconditionally or subject to conditions; or

(b) in respect of particular goods or classes of goods.

(2) A person who breaches a condition of such a consent commits an offence.

Penalty: $15 000.

Part 3 — Australian register of therapeutic goods

Division 1 — Preliminary

14. Therapeutic goods and gazetted groups (Cwlth s. 16)

(1) For the purposes of this Part, therapeutic goods are to be taken to be separate and distinct from other therapeutic goods if they have —

(a) a different formulation, composition or design specification;

(b) a different strength or size (disregarding pack size);

(c) a different dosage form or model;

(d) a different name;

(e) different indications;

(f) different directions for use; or

(g) a different type of container (disregarding container size).

(2) The Secretary may, by order published in the Commonwealth of Australia Gazette, determine that a group of therapeutic goods (not being therapeutic devices) identified in the order is a gazetted therapeutic goods group because the goods within the group have common characteristics.

(3) The Secretary may, by order published in the Commonwealth of Australia Gazette, determine that a group of therapeutic goods (being therapeutic devices) identified in the order is a gazetted therapeutic devices group because the goods within the group —

(a) have common characteristics; and

(b) have been produced by the same manufacturer.

(4) The Secretary may, by order published in the Commonwealth of Australia Gazette, determine that a group of kits identified in the order is a gazetted kits group.

(5) An order under subsection (2), (3) or (4) may make provision for or in relation to a matter by applying, adopting or incorporating, with or without modification, a document as in force from time to time, if the document is —

(a) published by the Commonwealth Department (whether in electronic form or otherwise);

(b) available for sale to the public; and

(c) available for inspection (whether by using a visual display unit or otherwise) by the public at offices of the Commonwealth Department specified by the Secretary in the order.

(6) The Secretary may, by order published in the Commonwealth of Australia Gazette, amend or revoke an order made under this section.

15. Offences relating to manufacture and supply of therapeutic goods (Cwlth s. 20)

(1) A person must not —

(a) manufacture in Western Australia therapeutic goods for use in humans; or

(b) supply therapeutic goods in Western Australia for use in humans;

unless —

(c) the goods are registered goods or listed goods in relation to the person;

(d) the goods are exempt goods or are the subject of an approval or authority under section 19 of the Commonwealth Act or section 8 of this Act; or

(e) the goods are the subject of an approval under section 19A of the Commonwealth Act.

Penalty: $25 000.

(2) It is a defence to a prosecution under subsection (1) if the defendant proves that the defendant was not a sponsor of the goods at the time of the manufacture or supply, as the case may be.

(3) A person in relation to whom therapeutic goods are registered or listed must not supply those goods in Western Australia unless —

(a) the registration number or listing number of the goods is set out on the label of the goods in the manner prescribed under the Commonwealth Act; or

(b) the goods are devices that are listed goods.

Penalty: $10 000.

16. Offence relating to supply of unregistered or unlisted goods (Cwlth s. 21)

A person must not supply in Western Australia therapeutic goods for use in humans (other than listable devices), being goods of which the person is not a sponsor, to another person unless —

(a) the goods are registered goods or listed goods;

(b) the goods are exempt goods or are the subject of an approval or authority under section 19 of the Commonwealth Act or under section 8 of this Act; or

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

Penalty: $15 000.

17. Hawking of therapeutic goods

A person must not supply unsolicited therapeutic goods in a street, by mail or from house to house other than in accordance with —

(a) the written approval of the Commissioner; or

(b) the regulations.

Penalty: $1 000.

18. Supply by automatic machine

(1) Subject to the regulations, a person must not whether in premises under his or her control or elsewhere —

(a) install an automatic machine for the supply of therapeutic goods; or

(b) supply therapeutic goods by means of an automatic machine.

(2) Subject to the regulations, a person must not permit an automatic machine for the supply of therapeutic goods to be installed on premises owned or occupied by that person.

(3) Subject to the regulations, a person must not permit therapeutic goods to be placed in an automatic machine under that person's control.

Penalty: $1 000.

19. General offences relating to this Part (Cwlth s. 22)

(1) A person must not set out or cause to be set out, on a container or package that contains therapeutic goods or on a label of goods of that kind, a number that purports to be the registration number or listing number of the goods in relation to a particular person if the number is not that number and the person knows,

or ought reasonably to know, that the number is not that number.

(2) A person must not, in or in connection with an application for listing of therapeutic goods make a statement that is false or misleading in a material particular if the person knows, or ought reasonably to know, that the statement is false or misleading in a material particular.

(3) A person in relation to whom therapeutic goods are registered or listed must not breach a condition of the registration or listing of the goods.

(4) A person must not —

(a) represent therapeutic goods that the person knows, or ought reasonably to know, are not included in the Register as being so included;

(b) represent therapeutic goods that the person knows, or ought reasonably to know, are not exempt goods as being exempt goods;

(c) represent therapeutic goods that the person knows, or ought reasonably to know, are included in one part of the Register as being included in the other part of the Register;

(d) represent therapeutic goods that the person knows, or ought reasonably to know, are not the subject of an approval or authority under section 19 of the Commonwealth Act or section 8 of this Act, as being the subject of such an approval of authority; or

(e) represent therapeutic goods that the person knows, or ought reasonably to know, are not the subject of an approval under section 19A of the Commonwealth Act as being the subject of such an approval.

(5) A person, being the sponsor of therapeutic goods that are included in the Register, must not, by any means, advertise the goods for an indication other than those that the person knows, or ought reasonably to know, are accepted in relation to the inclusion of the goods in the Register.

(6) A person must not make a claim, by any means, that the person or another person can arrange the supply of therapeutic goods (not being exempt goods) that the person knows, or ought reasonably to know, are not registered goods or listed goods.

(7) A person must not breach a condition of —

(a) an exemption applicable under regulations made for the purposes of section 18(1) of the Commonwealth Act;

(b) an approval under section 19 of the Commonwealth Act;

(c) an approval under section 19A of the Commonwealth Act; or

(d) an approval under section 8 of this Act.

(8) A person to whom an authority under section 19(5) of the Commonwealth Act or under section 8(5) of this Act has been granted must not supply the therapeutic goods to which the authority relates except in accordance with —

(a) the authority; and

(b) any regulations made for the purpose of section 19(7) of the Commonwealth Act.

(9) A person must not use therapeutic goods that the person knows, or ought reasonably to know, are not either exempt goods, listed goods, registered goods or goods the subject of an approval under section 19A of the Commonwealth Act —

(a) for use in the treatment of another person; or

(b) for use solely for experimental purposes in humans,

except in accordance with an approval or authority under section 19 of the Commonwealth Act or under section 8 of this Act.

Penalty: $10 000.

20. Offence to supply therapeutic goods for use in humans after expiry date, unless authorised by the Commissioner

A person must not supply therapeutic goods for use in humans after the expiry date that is, in accordance with a standard that is applicable to the goods, stated on or in relation to the goods, other than in accordance with the written approval of the Commissioner.

Penalty: $2 000.

21. Offence to use certain therapeutic devices without authority

A person must not use a therapeutic device of a type prescribed for the purposes of this section other than in accordance with an authorisation given by the Commissioner in accordance with the regulations.

Penalty: $5 000.

22. False statements in applications for registration (Cwlth s. 22A)

A person must not, in or in connection with an application for registration of therapeutic goods, make a statement that is false or misleading in a material particular if the person knows, or ought reasonably to know, that the statement is false or misleading in a material particular.

Penalty: $40 000.

Division 2 — Registration and listing

23. Applications generally (Cwlth s. 23)

(1) An application for registration or listing of therapeutic goods must —

(a) be made in accordance with a form approved, in writing, by the Secretary or in such other manner as is approved, in writing, by the Secretary; and

(b) be delivered to an office of the Commonwealth Department specified by the Secretary.

(2) An application is not effective unless —

(a) an application fee of an amount equal to the prescribed application fee under section 23 of the Commonwealth Act has been paid;

(b) the applicant has delivered to the office to which the application was made such information, in a form approved, in writing, by the Secretary, as will allow the determination of the application; and

(c) if the Secretary so requires, the applicant has delivered to the office to which the application was made a reasonable number of samples of the goods.

(3) An approval of a form may require or permit an application or information to be given in accordance with specified software requirements —

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

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

24. Applications for registration (Cwlth s. 24)

(1) Where an application is made for the registration of therapeutic goods in accordance with section 23 and the goods are goods

that are required to be registered, a fee of an amount equal to the fee specified in or determined in accordance with the Commonwealth regulations in relation to an application under section 24 of the Commonwealth Act is payable by the applicant in respect of the evaluation of the goods for registration, and the Secretary must notify each such applicant of the amount of the evaluation fee.

(2) Subject to section 28 of this Act, an application for registration of therapeutic goods lapses if —

(a) any part of the evaluation fee payable in respect of those goods remains unpaid at the end of the period of 2 months after the day on which the amount became due and payable;

(b) the application contains information that is inaccurate or misleading in a material particular;

(c) information given to the Secretary by, or on behalf of, the applicant in connection with the application, including information given for the purpose of a requirement under section 44 of this Act, is inaccurate or misleading in a material particular; or

(d) the applicant fails to comply with a requirement under section 44 of this Act to give information consisting of individual patient data in relation to the goods.

(3) In this section —

"individual patient data", in relation to therapeutic goods, means information, derived from clinical trials, relating to individuals before, during and after the administration of the goods to those individuals, including, but not limited to, demographic, biochemical and haematological information.

25. When evaluation fee due for payment (Cwlth s. 24A)

Subject to sections 26 and 28, an evaluation fee under section 24 payable by an applicant is due and payable on the day on which the applicant is notified of the amount of the evaluation fee.

26. Payment of evaluation fee by instalments (Cwlth s. 24B)

(1) If the Commonwealth regulations provide for the payment of an evaluation fee to be made by instalments under section 24B of the Commonwealth Act, the evaluation fee under section 24 of this Act may be made by such instalments and at such times as are ascertained in accordance with those Commonwealth regulations, and the evaluation fee is due and payable accordingly.

(2) If the Commonwealth regulations referred to in subsection (1) provide that a person is not allowed to pay an evaluation fee by instalments if any part of an instalment of that or any other evaluation fee payable by the person was unpaid immediately after the time when it became due for payment, a person is not allowed to pay an evaluation fee under section 24 of this Act in circumstances of that kind by instalments.

(3) Subsection (2) does not limit the generality of subsection (1).

27. Recovery of evaluation fee (Cwlth s. 24C)

An evaluation fee under section 24 may be recovered by the Commonwealth as a debt due to the Commonwealth.

28. Reduction of evaluation fee where evaluation not completed within prescribed period (Cwlth s. 24D)

(1) This section applies to an application under section 23 of this Act in relation to therapeutic goods for the evaluation of which

a period is prescribed under section 63(2)(da) of the Commonwealth Act.

(2) Nothing in section 24, 25 or 26 of this Act requires the applicant to pay more than three-quarters of the evaluation fee before the completion of the evaluation of the goods.

(3) If the evaluation is not completed within the period referred to in subsection (1), this Act has effect as if the evaluation fee were reduced to three-quarters of the fee that, under the Commonwealth regulations in relation to an application under section 24 of the Commonwealth Act, would have been the evaluation fee.

(4) If —

(a) the evaluation is completed within the period referred to in subsection (1); and

(b) part of the evaluation fee is unpaid when the evaluation is completed,

that part becomes due and payable on the completion of the evaluation.

(5) For the purposes of subsections (2), (3) and (4), the evaluation is to be taken to be completed when the applicant is notified according to section 30(3)(a) of the Secretary's decision on the application.

29. Deemed refusal of application (Cwlth s. 24E)

(1) This section applies in the case of an application under section 23 of this Act in relation to therapeutic goods for the evaluation of which a period is prescribed under section 63(2)(da) of the Commonwealth Act.

(2) If the evaluation is not completed within the period referred to in subsection (1), the applicant may give the Secretary written

notice that the applicant wishes to treat the application as having been refused.

(3) A notice under subsection (2) may be given at any time before the evaluation is completed.

(4) If a notice has been given, this Act has effect as if the Secretary had decided not to register the goods the subject of the application.

30. Evaluation and registration of therapeutic goods (Cwlth s. 25)

(1) Where —

(a) an application is made for the registration of therapeutic goods in relation to a person in accordance with section 23 of this Act;

(b) there is no part of an evaluation fee under section 24 of this Act in respect of those goods that —

(i) is due and payable by the person; and

(ii) remains unpaid;

and

(c) the person has complied with any requirements made by the Secretary under section 44 of this Act in relation to the goods,

the goods are to be evaluated for registration having regard to —

(d) whether the quality, safety and efficacy of the goods for the purposes for which they are to be used have been satisfactorily established;

(e) whether the presentation of the goods is acceptable;

(f) whether the goods conform to any standard applicable to the goods, or any requirements relating to advertising

applicable to goods of that kind under the Commonwealth regulations;

(g) if a step in the manufacture of the goods has been carried out outside Australia, whether the manufacturing and quality control procedures used in the manufacture of the goods are acceptable;

(h) if the goods have been manufactured in Western Australia, whether the goods have been manufactured in accordance with Part 4 of the Commonwealth Act or Part 4 of this Act;

(i) whether the goods contain substances that are prohibited imports for the purposes of the *Customs Act 1901* of the Commonwealth; and

(j) such other matters (if any) as the Secretary considers relevant.

Note: The Secretary must not use protected information when evaluating therapeutic goods for registration: see section 31 of this Act.

(2) In making a decision for the purposes of subsection (1)(g), the matters that may be taken into account include —

(a) whether the applicant has provided —

(i) if the goods are not therapeutic devices and a step in the manufacture of the goods has been carried out in a country that is a member of the European Community, a conformity assessment certificate in relation to the goods; or

(ii) in any other case, an acceptable form of evidence from a relevant overseas authority establishing that the manufacture of the goods is of an acceptable standard;

and

(b) whether the applicant has agreed to provide, where the Secretary considers inspection of the manufacturing procedures used in the manufacture of the goods to be necessary —

(i) funds for the carrying out of that inspection by the Commonwealth Department; and

(ii) evidence that the manufacturer has agreed to such an inspection.

(3) An evaluation under this section of goods in relation to which a period has been prescribed under section 63(2)(da) of the Commonwealth Act must be completed within that period.

(4) If therapeutic goods are exempt from the operation of Part 4 of the Commonwealth Act or Part 4 of this Act or a person is exempt from the operation of either or both of those Parts in relation to the manufacture of the goods, subsection (1) has effect, in relation to the goods, as if paragraph (h) were omitted.

(5) If a person is exempt from the operation of Part 4 of the Commonwealth Act or Part 4 of this Act in relation to a step in the manufacture of therapeutic goods, subsection (1) has effect, in relation to the goods, as if the reference in paragraph (h) to those Parts were a reference to those Parts to the extent that they apply to that person in relation to the manufacture of the goods.

(6) A decision for the purposes of paragraph (1)(g) may also take into account any information provided to the Secretary by a health authority of a Convention country and relating to —

(a) the general standards of manufacturing practice of a particular manufacturer; or

(b) the specific standards of manufacture or control adopted by a particular manufacturer in relation to particular goods.

(7) For the purposes of subsection (6), a Convention country is a country that is a party to the Mutual Recognition Convention.

(8) Information referred to in subsection (6) and provided in accordance with the Mutual Recognition Convention is to be treated as equivalent to information obtained as a result of an inspection under Part 4 of this Act.

(9) After therapeutic goods have been evaluated for registration, the Secretary must —

(a) notify the applicant in writing of his or her decision on the evaluation within 28 days of the making of the decision and, in the case of a decision not to register the goods, of the reasons for the decision; and

(b) if the decision is to register the goods, include the goods in the Register and give the applicant a certificate of registration.

(10) The registration of therapeutic goods commences on the day specified for the purpose in the certificate of registration.

(11) The failure to complete an evaluation within the period mentioned in subsection (3) does not render the Commonwealth, the State, the Secretary or a delegate of the Secretary liable to a person in respect of loss, damage or injury of any kind caused by, or arising out of, the failure.

31. When the Secretary must not use protected information (Cwlth s. 25A)

(1) If evaluating therapeutic goods for registration, the Secretary must not use information about other therapeutic goods that is protected information.

(2) In this section —

"protected information", in relation to therapeutic goods, means —

(a) that the information is protected information within the meaning of the Commonwealth Act; or

(b) that —

(i) the information was given by the Secretary in relation to an application to register therapeutic goods (the **"new goods"**) to which this Act applies —

(I) not being therapeutic devices; and

(II) consisting of, or containing, an active component;

(ii) the information is about the active component and is not available to the public;

(iii) when the application to register the new goods was lodged —

(I) no other therapeutic goods consisting of, or containing, that active component were included in the Register; and

(II) no such therapeutic goods had been included in the Register at any time before then;

(iv) 5 years have not passed since the goods became registered; and

(v) the person in relation to whom the new goods are registered has not given the Secretary permission in writing for the Secretary to use the information.

(3) For the purposes of subsection (2) —

"active component", in relation to therapeutic goods, means a substance that is, or one of the substances that together are, primarily responsible for the biological or other effect identifying the goods as therapeutic goods.

(4) The use of protected information contrary to subsection (1) does not render the Commonwealth, the State, the Secretary or a delegate of the Secretary liable to a person in respect of loss, damage or injury of any kind suffered as a result of, or arising out of, the use of that information.

32. Registration of therapeutic device to which conformity assessment certificate applies (Cwlth s. 25B)

(1) If —

(a) an application is made in accordance with section 23 for the registration of a therapeutic device in relation to a person; and

(b) the applicant gives to the Secretary a conformity assessment certificate as to the matters that would require evaluation under section 30(1) if that section applied in relation to the device,

then the Secretary must register the device unless the Secretary considers that the device may compromise the health or safety of users.

(2) The Secretary must notify the applicant in writing of his or her decision on the application within 28 days of the making of the decision and, if the Secretary decides not to register the device, the notice must contain the reasons for that decision.

(3) If the Secretary decides to register the device, the Secretary must —

(a) include the device in the Register; and

(b) give to the applicant a certificate of registration.

(4) The registration of the device commences on the day specified for the purpose in the certificate of registration.

33. Listing of therapeutic goods (Cwlth s. 26)

(1) If —

(a) an application is made in accordance with section 23 of this Act for the listing of therapeutic goods in relation to a person;

(b) the applicant has complied with any requirements made by the Secretary under section 44 of this Act in relation to the goods; and

(c) the goods are not goods which may be listed under section 35 of this Act,

then, subject to section 34 of this Act, the Secretary must not refuse to list the goods in relation to the person unless the Secretary is satisfied that —

(d) the goods are not eligible for listing;

(e) the goods are not safe for the purposes for which they are to be used;

(f) the presentation of the goods is unacceptable;

(g) the goods do not conform to a standard applicable to the goods or to a requirement relating to advertising applicable to goods of that kind under the Commonwealth regulations;

(h) if a step in the manufacture of the goods (not being therapeutic devices other than devices prescribed under the Commonwealth Act) for the purposes of section 26(1)(g) of the Commonwealth Act has been carried out outside Australia, the manufacturing and

quality control procedures used in the manufacture of the goods are not acceptable;

(i) if the goods have been manufactured in Western Australia, the goods have been manufactured contrary to Part 4 of the Commonwealth Act or Part 4 of this Act;

(j) the goods do not comply with quality or safety criteria prescribed under the Commonwealth Act; or

(k) the goods contain substances that are prohibited imports for the purposes of the *Customs Act 1901* of the Commonwealth.

(2) In making a decision for the purposes of subsection (1)(h), the matters that may be taken into account include —

(a) whether the applicant has provided —

(i) if the goods are not therapeutic devices and a step in the manufacture of the goods has been carried out in a country that is a member of the European Community, a conformity assessment certificate in relation to the goods; or

(ii) in any other case, an acceptable form of evidence from a relevant overseas authority establishing that the manufacture of the goods is of an acceptable standard;

and

(b) whether the applicant has agreed to provide, where the Secretary considers inspection of the manufacturing procedures used in the manufacture of the goods to be necessary —

(i) funds for the carrying out of that inspection by the Commonwealth Department; and

(ii) evidence that the manufacturer has agreed to such an inspection.

(3) If therapeutic goods are exempt from the operation of Part 4 of the Commonwealth Act or Part 4 of this Act or a person is exempt from the operation of either or both of those Parts in relation to the manufacture of the goods, subsection (1) has effect, in relation to the goods, as if paragraph (i) were omitted.

(4) If a person is exempt from the operation of Part 4 of the Commonwealth Act or Part 4 of this Act in relation to a step in the manufacture of therapeutic goods, subsection (1) has effect, in relation to the goods, as if the reference in paragraph (i) to those Parts were a reference to those Parts to the extent that they apply to that person in relation to the manufacture of the goods.

(5) A decision for the purposes of subsection (1)(h) may also take into account any information provided to the Secretary by a health authority of a Convention country and relating to —

(a) the general standards of manufacturing practice of a particular manufacturer; or

(b) the specific standards of manufacture or control adopted by a particular manufacturer in relation to particular goods.

(6) For the purposes of subsection (5), a Convention country is a country that is a party to the Mutual Recognition Convention.

(7) Information referred to in subsection (5) and provided in accordance with the Mutual Recognition Convention is to be treated as equivalent to information obtained as a result of an inspection under Part 4 of this Act.

(8) Where an application is made, the Secretary must notify the applicant in writing of his or her decision on the application within 28 days of the making of the decision and, in the case of a decision not to list the goods, of the reasons for the decision.

(9) As soon as practicable after an applicant has been informed that therapeutic goods in respect of which an application was made are acceptable for listing, the Secretary must give to the applicant a certificate of listing of the goods, and the listing of the goods commences on the day specified for the purpose in the certificate.

34. Listing of therapeutic devices to which conformity assessment certificate applies (Cwlth s. 26AA)

(1) If —

(a) an application is made in accordance with section 23 for the listing of a therapeutic device in relation to a person; and

(b) the applicant gives to the Secretary a conformity assessment certificate as to the matters specified in section 33(1)(d) to (k) in relation to the device,

then the Secretary must list the device in relation to the person unless the Secretary considers that the device may compromise the health or safety of users.

(2) The Secretary must notify the applicant in writing of his or her decision within 28 days of the making of the decision and if the Secretary decides not to list the device, the notice must contain the reasons for that decision.

(3) If the Secretary decides to list the device, the Secretary must —

(a) include the device in the Register; and

(b) give to the applicant a certificate of listing.

(4) The listing of the device commences on the day specified for the purpose in the certificate of listing.

35. Listing of certain types of therapeutic goods (Cwlth s. 26A)

(1) If —

(a) an application is made in accordance with section 23 of this Act for the listing of therapeutic goods in relation to a person;

(b) the applicant has complied with any requirements made by the Secretary under section 44 of this Act in relation to the goods;

(c) the requirements of subsection (2) and, where applicable, subsection (3) have been complied with; and

(d) the goods are not —

(i) therapeutic devices; or

(ii) device kits within the meaning of the regulations made for the purposes of section 26A(1)(d)(iv) of the Commonwealth Act,

then the Secretary is not to refuse to list the goods in relation to the person.

(2) The applicant must certify that —

(a) the goods are eligible for listing;

(b) the goods are safe for the purpose for which they are to be used;

(c) the presentation of the goods is not unacceptable;

(d) the goods conform to every standard, if any, applicable to the goods and to every requirement, if any, relating to advertising applicable under the regulations made under the Commonwealth Act or this Act;

(e) if the goods have been manufactured in Western Australia, each step in the manufacturing process has been carried out by a person who is the holder of a

licence to carry out that step granted under section 38 of the Commonwealth Act or section 50 of this Act;

(f) the goods comply with all quality of safety criteria prescribed under the Commonwealth Act;

(g) the goods do not contain substances that are prohibited imports for the purposes of the *Customs Act 1901* of the Commonwealth; and

(h) the information included in or with the application is correct.

(3) If a step in the manufacture of the goods has been carried out outside Australia, the Secretary must have certified, prior to the application being made, that the manufacturing and quality control procedures used in each such step are acceptable.

(4) In deciding whether so to certify for the purposes of subsection (3), the matters that may be taken into account include —

(a) whether the applicant has provided —

(i) if the goods are not therapeutic devices and a step in the manufacture of the goods has been carried out in a country that is a member of the European Community, a conformity assessment certificate in relation to the goods; or

(ii) in any other case, an acceptable form of evidence from a relevant overseas authority establishing that the manufacture of the goods is of an acceptable standard;

and

(b) whether the applicant has agreed to provide, if the Secretary considers inspection of the manufacturing procedures used in the manufacture of the goods to be necessary —

(i) funds for the carrying out of that inspection by the Department; and

(ii) evidence that the manufacturer has agreed to such an inspection.

(5) If therapeutic goods are exempt from the operation of Part 4 of the Commonwealth Act or Part 4 of this Act or a person is exempt from either or both of those Parts in relation to the manufacture of the goods, subsection (2) has effect, in relation to the goods, as if paragraph (e) were omitted.

(6) If a person (**"the manufacturer"**) is exempt from the operation of Part 4 of the Commonwealth Act or Part 4 of this Act in relation to a step in the manufacture of therapeutic goods, subsection (2) has effect in relation to the goods, as if the reference in paragraph (e) to a person who is the holder of a licence were a reference to the manufacturer to the extent those Parts apply to the manufacture of the goods.

(7) Where an application is made, the Secretary must notify the applicant in writing of his or her decision on the application within 28 days of the making of the decision and, in the case of a decision not to list the goods, of the reasons for the decision.

(8) As soon as practicable after an applicant has been informed that therapeutic goods in respect of which an application was made are acceptable for listing, the Secretary must give to the applicant a certificate of listing of the goods, and the listing of the goods commences on the day specified for the purpose in the certificate.

36. Registration or listing number (Cwlth s. 27)

(1) Where the Secretary includes therapeutic goods (other than grouped therapeutic goods) in the Register, the Secretary is to assign a unique registration or listing number to the goods.

(2) Where the Secretary includes grouped therapeutic goods in the Register, the Secretary is to assign a single, unique registration or listing number to the grouped therapeutic goods.

37. Conditions on registration or listing (Cwlth s. 28)

(1) Where the Secretary includes therapeutic goods in the Register in relation to a person the Secretary may, in writing, impose conditions on the registration or listing of those goods.

(2) Conditions referred to in subsection (1) may relate to —

(a) the manufacture of the goods;

(b) the custody, use, supply, disposal or destruction of the goods;

(c) the keeping of records relating to the goods;

(d) matters dealt with in, or matters additional to matters dealt with in, standards applicable to the goods; or

(e) such other matters relating to the goods as the Secretary thinks appropriate.

(3) The Secretary may, by notice in writing given to the person in relation to whom therapeutic goods are registered or listed, impose new conditions on the registration or listing or vary or remove existing conditions.

(4) The Secretary's power under subsection (3) may be exercised at the request of the person concerned or of the Secretary's own motion.

(5) The imposition or variation of a condition under subsection (3) takes effect —

(a) if the notice states that the action is necessary to prevent imminent risk of death, serious illness or serious injury, on the day on which the notice is given to the person; or

(b) in any other case, on the day specified for the purpose in the notice, being a day not earlier than 28 days after the notice is given to the person.

(6) In addition to any conditions imposed under subsection (1) or (3), the registration or listing of therapeutic goods is subject to the conditions that the person in relation to whom the goods are registered or listed will —

(a) allow an authorised person —

(i) to enter, at any reasonable time, premises at which the person deals with the goods; and

(ii) while on those premises, to inspect those premises and therapeutic goods at those premises and to take samples of goods of that kind;

and

(b) if requested to do so by an authorised person, produce to the person such documents relating to the goods as the person requires and allow the person to copy the documents.

(7) If —

(a) in, or in connection with, an application for the listing of therapeutic goods, a claim is made by the applicant in relation to the goods; and

(b) the claim is included in the Register in respect of the goods,

then the listing of the goods is subject to the following conditions —

(c) a condition that the sponsor of the goods had, at the time when the claim was made, information or evidence that supported the claim and complied with the requirements, if any, of the Commonwealth regulations;

(d) a condition that the sponsor retains the information or evidence at all times while the goods remain listed; and

(e) a condition that, at any time while the goods remain listed, the sponsor will, if asked by the Secretary, give information or evidence to the Secretary.

38. Duration of registration or listing (Cwlth s. 29)

Where goods are included in the Register in relation to a person, the goods remain so included until their registration or listing is cancelled under this Part.

39. Notification of adverse effects etc. of goods (Cwlth s. 29A)

(1) As soon as a person in relation to whom therapeutic goods are registered becomes aware of information of a kind mentioned in subsection (2) relating to the goods, the person must give the information to the Secretary in writing.

Penalty: $40 000.

(2) The information with which subsection (1) is concerned is information of the following kinds:

(a) information that contradicts information already furnished by the person under this Act;

(b) information that indicates that the use of the goods in accordance with the recommendations for their use may have an unintended harmful effect;

(c) information that indicates that the goods, when used in accordance with the recommendations for their use, may

not be as effective as the application for registration of the goods or information already furnished by the person under this Act suggests.

40. Notification of adverse effects etc. where application withdrawn or lapses (Cwlth s. 29B)

(1) If an application for registration of goods is withdrawn or lapses, the Secretary may give the applicant written notice requiring the applicant —

(a) to inform the Secretary in writing whether the applicant is aware of any information of a kind mentioned in section 39(2) relating to the goods; and

(b) if the applicant is aware of such information, to give the information to the Secretary in writing.

(2) Notice under subsection (1) may be given within 14 days after an application is withdrawn or lapses.

(3) A person must comply with the requirements of a notice under subsection (1) within 30 days after the notice is given to the person.

(4) A person must not, in purporting to comply with a notice under subsection (1), provide information that is false or misleading in a material particular if the person knows, or ought reasonably to know, that the information is false or misleading in a material particular.

Penalty: $40 000.

41. Cancellation of registration or listing (Cwlth s. 30)

(1) The Secretary may, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if —

(a) it appears to the Secretary that failure to cancel the registration or listing would create an imminent risk of death, serious illness or serious injury;

(b) the goods become exempt goods;

(c) the person requests in writing the cancellation of the registration or listing;

(d) the goods contain substances that are prohibited imports for the purposes of the *Customs Act 1901* of the Commonwealth; or

(e) in the case of goods listed under section 35, it appears to the Secretary that any of the certifications under section 35(2)(a), (e) or (g) are incorrect.

(2) Subject to subsection (3), the Secretary may, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if —

(a) it appears to the Secretary that the quality, safety or efficacy of the goods is unacceptable;

(b) the goods have changed so that they have become separate and distinct from the goods as so included;

(c) in the case of goods listed under section 35, it appears to the Secretary that any of the certifications under section 35(2)(b), (c), (d), (f) or (h) are incorrect;

(d) the sponsor has refused or failed to comply with a condition to which the inclusion of the goods is subject;

(e) the person has contravened section 39(1) in relation to the goods;

(f) the goods become required to be included in the other part of the Register;

(g) the goods do not conform to a standard applicable to the goods or to a requirement relating to advertising applicable to goods of that kind under the Commonwealth regulations or regulations made under this Act; or

(h) the annual registration or listing charge is not paid within 28 days after it becomes payable.

(3) Where the Secretary proposes to cancel the registration or listing of goods in relation to a person under subsection (2) otherwise than as a result of a failure to pay the annual registration or listing charge, the Secretary must —

(a) inform the person in writing that the Secretary proposes to cancel that registration or listing and set out the reasons for that proposed action; and

(b) give the person a reasonable opportunity to make submissions to the Secretary in relation to the proposed action.

(4) Where a person makes submissions in accordance with subsection (3)(b), the Secretary is not to make a decision relating to the cancellation until the Secretary has taken the submissions into account.

(5) The Secretary must, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration of the goods if the Secretary becomes aware that protected information was used when evaluating the goods for registration.

(6) Where the Secretary cancels the registration or listing of goods in relation to a person, the goods cease to be registered or listed —

(a) if the cancellation is effected under subsection (1), on the day on which the notice of cancellation is given to the person; or

(b) in any other case, on such later day as is specified in the notice.

(7) Where the Secretary cancels the registration or listing of goods in relation to a person, the Secretary —

(a) may, in writing, impose on the person one or both of the following requirements —

(i) to inform the public, or a specified class of persons, in the specified manner and within such reasonable period as is specified, of the cancellation;

(ii) to take steps to recover any of the goods that have been distributed;

and

(b) must cause to be published in the Commonwealth of Australia Gazette, as soon as practicable after the cancellation, a notice setting out particulars of the cancellation.

(8) A person who refuses or fails to comply with a requirement under subsection (7)(a) commits an offence.

Penalty: $10 000.

42. Recovery of wrongly supplied therapeutic goods (Cwlth s. 30A)

(1) This section applies if —

(a) any person supplies therapeutic goods; and

(b) the goods are not registered goods, listed goods, exempt goods, goods that are the subject of an approval or authority under section 19 of the Commonwealth Act or under section 8 of this Act, goods that are the subject of an approval under section 19A of the Commonwealth Act or an exemption under section 9 of this Act.

(2) The Secretary may, in writing, impose on the sponsor of the goods one or both of the following requirements —

(a) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, that the goods have been wrongly supplied;

(b) to take steps to recover any of the goods that have been distributed.

(3) The Secretary must cause to be published in the Commonwealth of Australia Gazette, as soon as practicable after imposing such a requirement, a notice setting out particulars of the requirement.

(4) A person who refuses or fails to comply with a requirement under subsection (2) commits an offence.

Penalty: $10 000.

43. Recovery etc. of registered or listed goods not conforming to standards (Cwlth s. 30B)

(1) This section applies if —

(a) therapeutic goods of a particular type are included in the Register in relation to a person;

(b) any person supplies a batch of goods of that kind;

(c) the Secretary is satisfied that the goods included in that batch do not conform to a standard applicable to goods of that kind; and

(d) the Secretary is not aware that any other goods of that kind supplied by the person within the previous 6 months have failed to conform to that standard or another standard applicable to goods of that kind.

(2) The Secretary may, in writing, impose on the sponsor of the goods one or both of the following requirements —

(a) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, that the goods included in that batch do not conform to a standard applicable to goods of that kind;

(b) to take steps to recover the goods included in that batch, except those goods that cannot be recovered because they have been administered to, or applied in the treatment of a person or animal.

(3) The Secretary must cause to be published in the Commonwealth of Australia Gazette, as soon as practicable after imposing such a requirement, a notice setting out particulars of the requirement.

(4) A person who refuses or fails to comply with a requirement under subsection (2) commits an offence.

Penalty: $10 000.

(5) This section does not stop the Secretary from taking action under section 41.

Division 3 — General

44. Secretary may require information (Cwlth s. 31)

(1) The Secretary may, by notice in writing given to a person who is an applicant for the registration of therapeutic goods or in relation to whom therapeutic goods are registered, require the person to give to the Secretary, within such reasonable time as is specified in the notice and in such form as is specified in the notice, information or documents relating to one or more of the following —

(a) the formulation of the goods;

(b) the composition of the goods;

(c) the design specifications of the goods;

(d) the quality of the goods;

(e) the method and place of manufacture or preparation of the goods and the procedures employed to ensure that proper standards are maintained in the manufacture and handling of the goods;

(f) the presentation of the goods;

(g) the safety and efficacy of the goods for the purposes for which they are to be used;

(h) the conformity of the goods to a requirement relating to advertising applicable to goods of that kind under the Commonwealth regulations;

(i) the regulatory history of the goods in another country;

(j) any other matter prescribed by the Commonwealth regulations for the purposes of section 31(1)(k) of the Commonwealth Act in relation to goods of that kind.

(2) The Secretary may, by notice in writing given to a person who is an applicant for the listing of therapeutic goods or in relation to whom therapeutic goods are listed, require the person to give to the Secretary, within such reasonable time as is specified in the notice and in such form as is specified in the notice, information or documents relating to one or more of the following —

(a) the formulation of the goods;

(b) the composition of the goods;

(c) the design specifications of the goods;

(d) the method and place of manufacture or preparation of the goods and the procedures employed to ensure that proper standards are maintained in the manufacture and handling of the goods;

(e) the presentation of the goods;

(f) the safety of the goods for the purposes for which they are to be used;

(g) the conformity of the goods to a standard applicable to the goods, or to a requirement relating to advertising applicable to goods of that kind under the Commonwealth regulations or regulations made under this Act;

(h) any other matter prescribed by the Commonwealth regulations for the purposes of section 31(2)(h) of the Commonwealth Act in relation to goods of that kind.

(3) A notice under this section requiring information or documents to be given may specify that the form in which the information or document is to be given is in accordance with specified software requirements —

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

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

(4) A person in relation to whom therapeutic goods are registered or listed must not, without reasonable excuse, fail to comply with a notice given to the person under this section.

Penalty: $10 000.

(5) A person in relation to whom therapeutic goods are registered or listed must not, in purporting to comply with a notice under this section, give information that is false or misleading in a material particular if the person knows, or ought reasonably to know, that the information is false or misleading in a material particular.

Penalty: $10 000.

45. Commissioner may obtain information about certain substances and goods

(1) The Commissioner may, by notice served on a person who manufactures in, imports into or supplies in Western Australia any therapeutic goods, require the person to give to the Commissioner, or to another person specified in the notice, such information about the goods as is requested in the notice.

(2) A person must comply with a notice within such time, being not less than 14 days after the notice is served, as is specified in the notice, unless the person has a reasonable excuse for not doing so.

(3) A notice may be served on a person even if the person has previously given information to the Commissioner about the goods.

(4) A person must not, in purporting to comply with a notice, give information that is false or misleading in a material particular if the person knows, or ought reasonably to know, that the information is false or misleading in a material particular.

Penalty: $2 000.

46. Inspection and variation of entries in Register (Cwlth s. 32)

(1) A person in relation to whom therapeutic goods are registered or listed may make a written request to the Secretary for a copy of the entry in the Register in relation to the goods.

(2) If a person makes such a request, the Secretary must send to the person a copy of so much, if any, of that entry as is contained in any computer database maintained by the Commonwealth Department for purposes connected with the administration of this Act, other than any part of that entry that was supplied in confidence by another person.

(3) If the person makes such a request, then, instead of providing a copy of an entry to the person, the Secretary may, if the request is for the provision of the copy in an electronic form, provide the information contained in the entry —

(a) on a data processing device; or

(b) by way of electronic transmission.

(4) The Secretary may, following a request by a person in relation to whom therapeutic goods are registered or listed or of his or her own motion, vary the entry in the Register in relation to the goods if the entry contains information that is incomplete or incorrect.

(5) Where —

(a) the person in relation to whom therapeutic goods are registered or listed has asked the Secretary to vary product information included in the entry in the Register that relates to the goods; and

(b) the only effect of the variation would be to reduce the class of persons for whom the goods are suitable or to add a warning or precaution, being a warning or precaution that does not include any comparison of the goods with any other therapeutic goods by reference to quality, safety or efficacy,

the Secretary must vary the entry in accordance with the request.

(6) Where —

(a) the person in relation to whom therapeutic goods are registered or listed has asked the Secretary to vary information included in the entry in the Register that relates to the goods;

(b) subsection (4) does not apply to the request; and

(c) the Secretary is satisfied that the variation requested does not indicate any reduction in the quality, safety or efficacy of the goods for the purposes for which they are to be used,

the Secretary may vary the entry in accordance with the request.

(7) In this section —

"product information", in relation to therapeutic goods, means information relating to the safe and effective use of the goods, including information regarding the usefulness and limitations of the goods.

47. Publication of list of goods on Register (Cwlth s. 33)

The Secretary must publish a list of the therapeutic goods included in the Register not less than once every 12 months.

Part 4 — Manufacturing of therapeutic goods

48. Offences relating to manufacturing and licences (Cwlth s. 35)

(1) A person must not, at premises in Western Australia, carry out a step in the manufacture of therapeutic goods for supply for use in humans unless —

(a) the goods are exempt goods or the person is an exempt person in relation to the manufacture of the goods; or

(b) the person is the holder of a licence under this Part or under Part 4 of the Commonwealth Act that authorises the carrying out of that step in relation to the goods at those premises.

Penalty: $25 000.

(2) A person who is the holder of a licence must not breach a condition of the licence.

Penalty: $15 000.

(3) A person must not, in or in connection with an application for a licence to manufacture therapeutic goods for use in humans, make a statement that is false or misleading in a material particular if the person knows, or ought reasonably to know, that it is false or misleading in a material particular.

Penalty: $10 000.

49. Application for licence (Cwlth s. 37)

(1) An application for a licence must —

(a) be made in writing in accordance with a form approved by the Secretary;

(b) identify the therapeutic goods or classes of therapeutic goods that the applicant proposes to manufacture;

(c) identify the manufacturing premises that will be used in the manufacture of those goods;

(d) identify the steps in the manufacture of those goods that the applicant proposes to carry out under the licence;

(e) state the names, qualifications and experience of the persons who are to have control of the production of the goods and of the quality control measures that are to be employed;

(f) be delivered to an office of the Commonwealth Department specified in the form; and

(g) be accompanied by an application fee of an amount equal to the application fee prescribed under the Commonwealth regulations in respect of an application under section 37 of the Commonwealth Act.

(2) The Secretary may, by notice in writing given to an applicant for a licence, require the applicant —

(a) to give to the Secretary, within such reasonable time as is specified in the notice, such further information concerning the application as is specified in the notice; or

(b) to allow an authorised person, at any reasonable time specified in the notice, to inspect the premises, equipment, processes and facilities that will be used in the manufacture of the goods, or other goods on those premises.

50. Grant of licence (Cwlth s. 38)

(1) Where —

(a) a person has made an application to carry out steps in the manufacture of therapeutic goods at particular manufacturing premises;

(b) an application fee of an amount equal to the application fee prescribed under the Commonwealth regulations in respect of an application under section 37 of the Commonwealth Act has been paid;

(c) fees of an amount equal to any applicable inspection fees prescribed under the Commonwealth regulations in respect of the grant of a licence under section 38 of the Commonwealth Act have been paid; and

(d) the person has complied with any requirements made by the Secretary under section 49(2) of this Act in relation to the application,

the Secretary must grant the person a licence to carry out those steps at those premises unless —

(e) the Secretary is satisfied that —

(i) the person will be unable to comply with the manufacturing principles; or

(ii) the premises are not satisfactory for the manufacture of the goods;

(f) the person —

(i) has had a licence granted to the person under this Act or the Commonwealth Act revoked;

(ii) has been convicted of an offence against this Act, the Commonwealth Act or a law of another State or Territory relating to therapeutic goods;

(iii) controls a body corporate, whether directly or indirectly through one or more interposed entities, that has been convicted of an offence against this Act, the Commonwealth Act or a law of a State or Territory relating to therapeutic goods;

(iv) controlled a body corporate, whether directly or indirectly through one or more interposed entities, when the body committed an offence against this Act, the Commonwealth Act or a law of a State or Territory relating to therapeutic goods for which the body has been convicted;

(v) is controlled by another person, whether directly or indirectly through one or more interposed entities, and that other person has been convicted of an offence against this Act, the Commonwealth Act or a law of a State or Territory relating to therapeutic goods; or

(vi) has failed on more than one occasion to observe the manufacturing principles in connection with the manufacture of therapeutic goods.

(2) Despite subsection (1)(f), the Secretary may grant a licence to a person who, apart from this subsection, could not be granted a licence because of subsection (1)(f) if, in the opinion of the Secretary, special circumstances make it appropriate to do so.

(3) Where the Secretary grants or refuses to grant a licence to a person, the Secretary must —

(a) give the person written notice of the decision; and

(b) in the case of a refusal, include in the notice the reasons for the refusal.

(4) Where the Secretary grants a licence, the Secretary must cause particulars of the decision to be published in the Commonwealth of Australia Gazette as soon as is practicable after the decision is made.

51. Term of licence (Cwlth s. 39)

A licence commences on the day specified in the licence and remains in force until it is revoked or suspended.

52. Conditions of licences (Cwlth s. 40)

(1) A licence may be granted subject to —

(a) conditions designed to ensure that the holder of the licence manufactures the goods in accordance with the manufacturing principles and any standards applicable to the goods; and

(b) such other conditions relating to the manufacture of the goods as the Secretary thinks appropriate.

(2) The Secretary may, by notice in writing given to the holder of a licence, impose new conditions on the licence or vary or remove existing conditions.

(3) The imposition or variation of a condition under subsection (2) takes effect —

(a) if the notice states that the action is necessary to prevent imminent risk of death, serious illness or serious injury, on the day on which the notice is given to the person; or

(b) in any other case, on the day specified for the purpose in the notice, being a day not earlier than 28 days after the notice is given to the person.

(4) In addition to any conditions imposed under subsection (1) or (2), each licence is, except as otherwise specified in the licence, subject to the conditions that the holder of the licence will —

(a) ensure that the goods conform to any standard applicable to the goods;

(b) allow an authorised person —

(i) to enter, at any reasonable time, the manufacturing premises to which the licence relates; and

(ii) while on those premises, to inspect those premises, any therapeutic goods manufactured at those premises and processes relating to that manufacture, and to take samples of goods of that kind and, with the agreement of the holder, to take photographs of those premises, goods or processes;

(c) where an authorised person enters premises as mentioned in paragraph (b)(i), answer questions relating to procedures carried out at the premises and require employees at those premises to do so;

(d) if requested to do so by an authorised person —

(i) produce to the person such documents relating to the manufacture of therapeutic goods manufactured at those premises as the person requires and allow the person to copy the documents; or

(ii) produce to the person for examination any batch samples kept by the holder;

and

(e) comply with such other conditions (if any) as are specified in the Commonwealth regulations for the purposes of section 40 of the Commonwealth Act.

53. Revocation and suspension of licences (Cwlth s. 41)

(1) Subject to subsection (2), the Secretary may, by notice in writing given to the holder of a licence, revoke the licence, or suspend the licence for a period specified in the notice, if —

(a) the holder has been convicted of an offence against this Act or the Commonwealth Act;

(b) the holder controls a body corporate, whether directly or indirectly through one or more interposed entities, that has been convicted of an offence against this Act, the Commonwealth Act or a law of a State or Territory relating to therapeutic goods;

(c) the holder controlled a body corporate, whether directly or indirectly through one or more interposed entities, when the body committed an offence against this Act, the Commonwealth Act or a law of a State or Territory relating to therapeutic goods for which the body has been convicted;

(d) the holder is controlled by another person, whether directly or indirectly through one or more interposed entities, and that other person has been convicted of an offence against this Act, the Commonwealth Act or a law of a State or Territory relating to therapeutic goods;

(e) the holder has breached a condition of the licence;

(f) the holder has failed to observe the manufacturing principles;

(g) the holder requests in writing that the licence be revoked or suspended, as the case may be;

(h) the holder ceases to carry on the business of manufacturing the goods to which the licence relates; or

(i) the annual licensing charge, or any applicable inspection fees, have not been paid within 28 days after they become payable.

(2) Where the Secretary proposes to revoke a licence or suspend a licence otherwise than at the request of the holder of the licence, the Secretary must, unless the Secretary considers that failure to revoke or suspend the licence immediately would create an imminent risk of death, serious illness or serious injury —

(a) by notice in writing given to the holder, inform the holder of the action that the Secretary proposes to take and of the reasons for that proposed action; and

(b) except where the proposed action is to be taken as a result of a failure to pay the annual licensing charge or an applicable inspection fee, give the holder an opportunity to make, within such reasonable time as is specified in the notice, submissions to the Secretary in relation to the proposed action.

(3) Where the holder makes submissions in accordance with subsection (2)(b), the Secretary is not to make a decision relating to the revocation or suspension of the licence before taking into account the submissions.

(4) A licence may be revoked even if the licence is suspended.

(5) Where a licence is suspended, the Secretary may, by notice in writing given to the holder of the licence, revoke the suspension.

(6) Where the Secretary revokes or suspends a licence, the Secretary must cause particulars of the decision to be published in the Commonwealth of Australia Gazette as soon as practicable after the decision is made.

54. Publication of list of manufacturers etc. (Cwlth s. 42)

The Secretary may, from time to time and in such manner as the Secretary determines, publish a list of the persons who are licensed under this Part, the classes of goods to which the

licences relate, the steps of manufacture that the licences authorise and the addresses of the manufacturing premises to which the licences relate.

Part 5 — Wholesalers to comply with code of practice

55. Wholesalers to comply with wholesaling code of practice

(1) A person who is engaged in the supply by wholesale of therapeutic goods for human use must ensure that the recommendations and requirements of the *Wholesaling Code of Practice* are complied with.

Penalty: $10 000.

(2) In this section —

"supply by wholesale" —

(a) means supply for the purposes of resale; and

(b) includes supply in wholesale quantities of therapeutic goods for use —

(i) in a public institution; or

(ii) in connection with a profession, business, trade or industry for use only in connection with that profession, business, trade or industry, but not for resale.

"Wholesaling Code of Practice" means the code of practice entitled Code of Good Wholesaling Practice for Therapeutic Goods for Human Use, published by the Commonwealth Government, as in force from time to time.

(3) Nothing in this section affects the operation of any other provision of this Act in relation to the supply of therapeutic goods.

Part 6 — Payment of charges

56. By whom charges payable (Cwlth s. 43)

(1) An annual registration charge is payable by the person in relation to whom therapeutic goods are registered.

(2) An annual listing charge is payable by the person in relation to whom therapeutic goods are listed.

(3) An annual licensing charge is payable by the holder of a licence under Part 4.

57. Time for payment of charges (Cwlth s. 44)

(1) An annual registration charge or annual listing charge for a financial year relating to therapeutic goods other than grouped therapeutic goods becomes payable —

(a) if the year is the financial year (in this subsection called the **"first year"**) during which the registration or listing of the therapeutic goods concerned commenced, on that commencement; or

(b) if the year is a later financial year, on the anniversary of that commencement or, if the Secretary has, by notice in writing given before the end of the first year to the person in relation to whom the therapeutic goods concerned are registered or listed, specified another day as being the day on which the charge becomes payable, on the specified day or on an anniversary of that day, as the case requires.

(2) An annual registration charge or annual listing charge for a financial year relating to grouped therapeutic goods becomes payable by a person on the day specified in relation to those grouped therapeutic goods in a written notice given by the Secretary to the person.

(3) An annual licensing charge for a financial year becomes payable on the day on which the licence commenced and on each anniversary of that day.

(4) The Secretary may, by agreement with the person by whom an annual registration charge, annual listing charge or an annual licensing charge is payable, vary the day on which the charge is payable.

58. Recovery of charges

An annual registration charge, annual listing charge or annual licensing charge may be recovered by the Commonwealth as a debt due to the Commonwealth.

Part 7 — Entry, searches and warrants

59. Definitions in this Part (Cwlth s. 45A)

In this Part, unless the contrary intention appears —

"evidential material" means —

(a) any thing with respect to which an offence against this Act has been committed or is suspected, on reasonable grounds, to have been committed;

(b) any thing as to which there are reasonable grounds for suspecting that it will afford evidence as to the commission of any such offence; or

(c) any thing as to which there are reasonable grounds for suspecting that it is intended to be used for the purpose of committing any such offence;

"occupier" , in relation to premises, includes a person present at the premises who is in apparent control of the premises;

"seize" includes secure against interference;

"thing" includes a substance, and a thing in electronic or magnetic form.

60. Searches to monitor compliance with Act (Cwlth s. 46)

(1) Subject to subsections (2) and (3), an authorised person may, for the purpose of finding out whether this Act or the regulations have been complied with —

(a) enter any premises; and

(b) exercise the powers set out in section 64(1).

(2) The authorised person must not enter the premises unless —

(a) the occupier of the premises has consented to the entry; or

(b) the entry is made under a warrant issued under section 74.

(3) An authorised person is not entitled to exercise any powers under subsection (1) in relation to the premises if —

(a) the occupier of the premises has required the authorised person to produce his or her identity card for inspection by the occupier; and

(b) the authorised person fails to comply with the requirement.

61. Searches of certain premises to monitor compliance with Act (Cwlth s. 46A)

(1) An authorised person may, subject to subsections (2) and (3), and to the extent that it is reasonably necessary for the purpose of finding out whether this Act or the regulations have been complied with, enter premises to which this section applies and do any of the following —

(a) search the premises and any thing on the premises;

(b) inspect, examine, take measurements of, or conduct tests, including by the taking of samples, concerning, any thing in the premises that relates to therapeutic goods;

(c) take photographs, including video recordings, or make sketches of the premises or any thing on the premises;

(d) inspect any book, record, or document on the premises.

(2) An authorised person must not, under subsection (1), enter premises that are a residence unless —

(a) the occupier of the premises has consented to the entry; or

(b) the premises are used for commercial purposes in relation to therapeutic goods, in addition to residential purposes.

(3) An authorised person is not entitled to exercise any powers under subsection (1) in relation to premises if —

(a) the occupier of the premises has required the authorised person to produce his or her identity card for inspection by the occupier;

(b) the authorised person fails to comply with the requirement.

(4) This section applies to —

(a) premises of a person —

(i) who has been granted an approval or authority under section 19 of the Commonwealth Act or under section 8 of this Act, or an exemption under section 9 of this Act;

(ii) who has been granted approval under section 19A of the Commonwealth Act; or

(iii) in relation to whom therapeutic goods are registered or listed,

being premises connected with the manufacture or supply of therapeutic goods or the keeping of records relating to the manufacture or supply of therapeutic goods;

(b) premises to which the person in relation to whom therapeutic goods are registered or listed, or the sponsor of the goods, must allow access as a condition of the registration or listing of the therapeutic goods; and

(c) premises in relation to which a licence has been granted under Part 4 of the Commonwealth Act or Part 4 of this Act for the manufacture of therapeutic goods, or

premises at which records are kept in relation to such information.

62. Searches and seizures on public health grounds (Cwlth s. 46B)

(1) Subject to subsection (2), if an authorised person has reasonable grounds for suspecting that —

(a) there may be on any premises a particular thing in respect of which this Act or the regulations have not been complied with; and

(b) it is necessary in the interests of public health to exercise powers under this section in order to avoid an imminent risk of death, serious illness or serious injury,

the authorised person may, to the extent that it is reasonably necessary for the purpose of avoiding an imminent risk of death, serious illness or serious injury, enter the premises and do any of the following —

(c) search the premises for the thing;

(d) if the authorised person finds the thing on the premises, seize it.

(2) An authorised person is not entitled to exercise any powers under subsection (1) in relation to premises if —

(a) the occupier of the premises has required the authorised person to produce his or her identity card for inspection by the occupier; and

(b) the authorised person fails to comply with the requirement.

63. Searches and seizures related to offences (Cwlth s. 47)

(1) Subject to subsections (2) and (3), if an authorised person has reasonable grounds for suspecting that there may be evidential material on any premises, the authorised person may —

(a) enter the premises;

(b) exercise the powers set out in subsection (4) and section 64(1); and

(c) if the authorised person finds the thing on the premises, seize it.

(2) The authorised person must not enter the premises unless —

(a) the occupier of the premises has consented to the entry; or

(b) the entry is made under a warrant issued under section 75.

(3) An authorised person is not entitled to exercise any powers under subsection (1) in relation to premises if —

(a) the occupier of the premises has required the authorised person to produce his or her identity card for inspection by the occupier; and

(b) the authorised person fails to comply with the requirement.

(4) If —

(a) in the course of searching, in accordance with a warrant, for a particular thing, an authorised person finds another thing that the authorised person believes on reasonable grounds to be evidential material; and

(b) the authorised person believes, on reasonable grounds, that it is necessary to seize that other thing in order to prevent its concealment, loss or destruction, or its use in

committing, continuing or repeating an offence against this Act,

the warrant is taken to authorise the authorised person to seize that other thing.

64. General powers of authorised persons in relation to premises (Cwlth s. 48)

(1) The powers an authorised person may exercise under sections 60(1)(b) and 63(1)(b) are as follows —

(a) to search the premises and any thing on the premises;

(b) to inspect, examine, take measurements of, or conduct tests, including by the taking of samples, concerning any thing on the premises that relates to therapeutic goods;

(c) to take photographs, including video recordings, or make sketches of the premises or any thing on the premises;

(d) if the authorised person was only authorised to enter the premises because the occupier of the premises consented to the entry, to require the occupier to —

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

(ii) produce any book, record or document requested by the authorised person;

(e) if the authorised person was authorised to enter the premises by a warrant under section 74 or 75, to require any person on or in the premises to —

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

(ii) produce any book, record or document requested by the authorised person;

(f) to inspect any book, record or document on the premises;

(g) to take extracts from or make copies of any such book, record or document;

(h) to take onto the premises such equipment and materials as the authorised person requires for the purpose of exercising powers in relation to the premises.

(2) A person must not, without reasonable excuse, refuse or fail to comply with a requirement under subsection (1)(e).

Penalty: $3 000.

(3) It is a reasonable excuse for a person to refuse or fail to answer a question or produce a document if answering the question, or producing the document, would tend to incriminate the person.

65. Details of warrants to be given to occupier etc. (Cwlth s. 48A)

(1) If a warrant in relation to premises is being executed and the occupier of the premises or another person who apparently represents the occupier is present at the premises, the authorised person must make available to that person a copy of the warrant.

(2) The authorised person must identify himself or herself to that person.

(3) The copy of the warrant referred to in subsection (1) need not include the signature of the magistrate who issued the warrant.

66. Announcement before entry (Cwlth s. 48B)

(1) An authorised person must, before entering the premises under a warrant —

(a) announce that he or she is authorised to enter the premises; and

(b) give any person at the premises an opportunity to allow entry to the premises.

(2) An authorised person is not required to comply with subsection (1) if he or she believes on reasonable grounds that immediate entry to the premises is required to ensure —

(a) the safety of a person; or

(b) that the effective execution of the warrant is not frustrated.

67. Use of electronic equipment at premises (Cwlth s. 48C)

(1) The authorised person may operate electronic equipment at the premises to see whether evidential material is accessible by doing so if he or she believes on reasonable grounds that the operation of the equipment can be carried out without damage to the equipment.

(2) If the authorised person, after operating the equipment, finds that evidential material is accessible by doing so, he or she may —

(a) seize the equipment and any disk, tape or other associated device;

(b) if the material can, by using facilities at the premises, be put in documentary form, operate the facilities to put the material in that form and seize the documents so produced; or

(c) if the material can be transferred to a disk, tape or other storage device that —

(i) is brought to the premises; or

(ii) is at the premises and the use of which for the purpose has been agreed to in writing by the occupier of the premises,

operate the equipment or other facilities to copy the material to the storage device and take the storage device from the premises.

(3) An authorised person may seize equipment under subsection (2)(a) only if —

(a) it is not practicable to put the material in documentary form as mentioned in subsection (2)(b) or to copy the material as mentioned in subsection (2)(c); or

(b) possession by the occupier of the equipment could constitute an offence.

(4) If the authorised person believes on reasonable grounds that —

(a) evidential material may be accessible by operating electronic equipment at the premises;

(b) expert assistance is required to operate the equipment; and

(c) if he or she does not take action under this subsection, the material may be destroyed, altered or otherwise interfered with,

he or she may do whatever is necessary to secure the equipment, whether by locking it up, placing a guard or otherwise.

(5) The authorised person must give notice to the occupier of the premises of his or her intention to secure equipment and of the fact that the equipment may be secured for up to 24 hours.

(6) The equipment may be secured —

(a) for a period not exceeding 24 hours; or

(b) until the equipment has been operated by the expert,

whichever occurs first.

(7) If the authorised person believes on reasonable grounds that the expert assistance will not be available within 24 hours, he or she may apply to the magistrate for an extension of that period.

(8) The authorised person must give notice to the occupier of the premises of his or her intention to apply for an extension, and the occupier is entitled to be heard in relation to the application.

68. Compensation for damage to electronic equipment (Cwlth s. 48D)

(1) If —

(a) damage is caused to equipment as a result of it being operated as mentioned in section 67; and

(b) the damage was caused as a result of —

(i) insufficient care being exercised in selecting the person who was to operate the equipment; or

(ii) insufficient care being exercised by the person operating the equipment,

compensation for the damage is payable to the owner of the equipment.

(2) Compensation is payable out of the Consolidated Fund, which is to the necessary extent appropriated accordingly.

(3) In determining the amount of compensation payable, regard is to be had to whether the occupier of the premises and his or her employees and agents, if they were available at the time, had provided any warning or guidance as to the operation of the equipment that was appropriate in the circumstances.

69. Copies of seized things to be provided (Cwlth s. 48E)

(1) Subject to subsection (2), if an authorised person seizes, under a warrant relating to premises —

(a) a document, film, computer file or other thing that can be readily copied; or

(b) a storage device the information in which can be readily copied,

the authorised person must, if requested to do so by the occupier of the premises or another person who apparently represents the occupier and who is present when the warrant is executed, give a copy of the thing or the information to that person as soon as practicable after the seizure.

(2) Subsection (1) does not apply if —

(a) the thing that has been seized or taken was seized or taken under section 67(2)(b) or (c); or

(b) possession by the occupier of the document, film, computer file, thing or information could constitute an offence.

70. Occupier entitled to be present during search (Cwlth s. 48F)

(1) If a warrant in relation to premises is being executed and the occupier of the premises or another person who apparently represents the occupier is present at the premises, the person is entitled to observe the search being conducted.

(2) The right to observe the search being conducted ceases if the person impedes the search.

(3) This section does not prevent 2 or more areas of the premises being searched at the same time.

71. Receipts for things seized under warrant (Cwlth s. 48G)

(1) If a thing is seized under this Part, the authorised person must provide a receipt for the thing.

(2) If 2 or more things are seized or moved, they may be covered in the one receipt.

72. Retention of seized things (Cwlth s. 48H)

(1) Subject to any contrary order of a court, if an authorised person seizes a thing under this Part, an authorised person must return it if —

(a) the reason for its seizure no longer exists or it is decided that it is not to be used in evidence; or

(b) subject to subsection (2), the period of 90 days after its seizure ends,

whichever first occurs, unless the thing is forfeited or forfeitable under this Act or the Commonwealth Act.

(2) At the end of the 90 days specified in subsection (l)(b) an authorised person must take reasonable steps to return the thing to the person from whom it was seized, unless —

(a) proceedings in respect of which the thing may afford evidence were instituted before the end of the 90 days and have not been completed, including an appeal to a court in relation to those proceedings;

(b) an authorised person may retain the thing because of an order under section 73; or

(c) an authorised person is otherwise authorised (by a law, or an order of a court, of the Commonwealth or of a State or Territory) to retain, destroy or dispose of the thing.

(3) The thing may be returned under subsection (2) either unconditionally or on such terms and conditions —

(a) as the Commissioner sees fit, if the thing is seized by a person authorised under section 7(1) or a member of the Police Force of Western Australia; or

(b) as the Secretary sees fit in any other case.

73. Magistrate may permit a thing to be retained (Cwlth s. 48J)

(1) An authorised person may apply to a magistrate for an order that he or she may retain the thing for a further period if —

(a) before the end of 90 days after the seizure; or

(b) before the end of a period previously specified in an order of a magistrate under this section,

proceedings in respect of which the thing may afford evidence have not commenced.

(2) If the magistrate is satisfied that it is necessary for an authorised person to continue to retain the thing —

(a) for the purposes of an investigation as to whether an offence against this Act has been committed; or

(b) to enable evidence of an offence against this Act to be secured for the purposes of a prosecution,

the magistrate may order that an authorised person may retain the thing for the period, not exceeding 3 years, specified in the order.

(3) Before making the application, the authorised person must —

(a) take reasonable steps to discover who has an interest in the retention of the thing; and

(b) if it is practicable to do so, notify each person whom the authorised person believes to have such an interest of the proposed application.

74. Monitoring warrants (Cwlth s. 49)

(1) An authorised person may apply to a justice for a warrant under this section in relation to premises.

(2) Subject to subsection (3), a justice may issue the warrant if satisfied, by information on oath, that it is reasonably necessary that one or more authorised persons should have access to the premises for the purpose of finding out whether the requirements of this Act are being complied with.

(3) A justice is not to issue a warrant unless the authorised person or some other person has given to the justice, either orally or by affidavit, such further information (if any) as the justice requires concerning the grounds on which the issue of the warrant is being sought.

(4) The warrant must —

(a) authorise one or more authorised persons, whether or not named in the warrant, with such assistance and by such force as is necessary and reasonable —

(i) to enter the premises; and

(ii) to exercise the powers set out in section 64(1) in relation to the premises;

(b) state whether the entry is authorised to be made at any time of the day or night or during specified hours of the day or night;

(c) specify the day (not more than 6 months after the issue of the warrant) on which the warrant ceases to have effect; and

(d) state the purpose for which the warrant is issued.

75. Offence related warrants (Cwlth s. 50)

(1) An authorised person may apply to a justice for a warrant under this section in relation to premises.

(2) Subject to subsection (3), a justice may issue the warrant if satisfied, by information on oath, that there are reasonable grounds for suspecting that there is, or there may be within the next 72 hours, in or on the premises evidential material.

(3) A justice must not issue a warrant unless the authorised person or some other person has given to the justice, either orally or by affidavit, such further information (if any) as the justice requires concerning the grounds on which the issue of the warrant is sought.

(4) The warrant must —

(a) name one or more authorised persons;

(b) authorise the persons so named, with such assistance and by such force as is necessary and reasonable —

(i) to enter the premises;

(ii) to exercise the powers set out in sections 63(4) and 64(1); and

(iii) to seize the evidential material;

(c) state whether the entry is authorised to be made at any time of the day or night or during specified hours of the day or night;

(d) specify the day (not more than one week after the issue of the warrant) on which the warrant ceases to have effect; and

(e) state the purpose for which the warrant is issued.

76. Offence related warrants by telephone (Cwlth s. 51)

(1) If, in an urgent case, an authorised person considers it necessary to do so, the person may apply to a magistrate by telephone for a warrant under section 75 in relation to premises.

(2) Before applying for a warrant, the person must prepare an information of the kind mentioned in section 75(2) in relation to the premises that sets out the grounds on which the warrant is sought.

(3) If it is necessary to do so, the person may apply for the warrant before the information is sworn.

(4) If the magistrate is satisfied —

(a) after having considered the terms of the information; and

(b) after having received such further information (if any) as the magistrate requires concerning the grounds on which the issue of the warrant is being sought,

that there are reasonable grounds for issuing the warrant, the magistrate may complete and sign the same warrant that could be issued under section 75 if the application had been made under that section.

(5) If the magistrate completes and signs the warrant —

(a) the magistrate must —

(i) tell the authorised person what the terms of the warrant are;

(ii) tell the authorised person the day on which and the time at which the warrant was signed;

(iii) tell the authorised person the day, not more than one week after the magistrate completes and

signs the warrant, on which the warrant ceases to have effect; and

(iv) record on the warrant the reasons for granting the warrant;

and

(b) the authorised person must —

(i) complete a form of warrant in the same terms as the warrant completed and signed by the magistrate; and

(ii) write on the form the name of the magistrate and the day on which and the time at which the warrant was signed.

(6) The authorised person must also, not later that the day after the day of expiry or execution of the warrant, whichever is the earlier, send to the magistrate —

(a) the form of the warrant completed by the person; and

(b) the information referred to in subsection (2), which must have been duly sworn.

(7) When the magistrate receives those documents, the magistrate must —

(a) attach them to the warrant that the magistrate completed and signed; and

(b) deal with them in the way in which the magistrate would have dealt with the information if the application had been made under section 75.

(8) A form of warrant duly completed under subsection (5) is authority for any entry, search, seizure or other exercise of a power that the warrant signed by the magistrate authorises.

(9) If —

(a) it is material, in any proceedings, for a court to be satisfied that an exercise of power was authorised by this section; and

(b) the warrant signed by the magistrate authorising the exercise of the power is not produced in evidence,

the court must assume, unless the contrary is proved, that the exercise of the power was not authorised by such a warrant.

(10) A reference in this Part to a warrant under section 75 includes a reference to a warrant signed by a magistrate under this section.

77. Offences relating to warrants (Cwlth s. 51B)

(1) A person must not, in an application for a warrant, make a statement that is false or misleading in a material particular if the person knows, or ought reasonably to know, that the statement is false or misleading in a material particular.

Penalty: Imprisonment for 2 years.

(2) A person must not —

(a) state in a document that purports to be a form of warrant under section 76 the name of the magistrate unless that magistrate issued the warrant;

(b) state on a form of warrant under that section a matter that, to the person's knowledge, departs in a material particular from the form authorised by the magistrate;

(c) purport to execute, or present to another person, a document that purports to be a form of warrant under that section that the first mentioned person knows —

(i) has not been approved by a magistrate under that section; or

(ii) to depart in a material particular from the terms authorised by the magistrate under that section;

or

(d) give to a magistrate a form of warrant under that section that is not the form of warrant that the person purported to execute.

Penalty: Imprisonment for 2 years.

Part 8 — Miscellaneous

78. Identity cards (Cwlth s. 52)

(1) The Commissioner is to ensure that each person authorised by him or her as an authorised person for the purposes of this Act is issued with an identity card that incorporates a recent photograph of the person.

(2) Where a person ceases to be an authorised person referred to in subsection (1), the person must, as soon as practicable after so ceasing, return the person's identity card to the Commissioner.

Penalty: $1 000.

79. Indictable offences and forfeiture (Cwlth s. 54)

(1) An offence against section 22, 39 or 40 is an indictable offence.

(2) Despite subsection (1), a court of summary jurisdiction may hear and determine proceedings in respect of an offence referred to in subsection (1) if the court is satisfied that it is appropriate to do so and the defendant and the prosecutor consent.

(3) Where a court of summary jurisdiction convicts a person of an offence referred to in subsection (1), the penalty that the court may impose is a fine not exceeding $2 000.

(4) If a court convicts a person of an offence against this Act in relation to any therapeutic goods, the court may order that the goods be forfeited to the State and, where such an order is made, the goods become the property of the State.

(5) Where goods are so forfeited, the Commissioner may cause notice of the forfeiture to be published in the *Gazette*.

(6) Goods forfeited under an order referred to in subsection (2) are to be disposed of in such manner as the Commissioner directs.

80. Time for bringing prosecutions (Cwlth s. 54A)

Proceedings for an offence against this Act may be commenced within 3 years after the alleged commission of the offence, but not later.

81. Evidentiary certificate of Commissioner

(1) In any legal proceedings under this Act, a certificate purporting to be signed by the Commissioner as to any of the matters set out in subsection (2) is evidence and, in the absence of evidence to the contrary, is proof of the facts stated in the certificate.

(2) The Commissioner may certify as to the following —

(a) a person was or was not, at a date specified in the certificate —

(i) the holder of a licence under this Act;

(ii) the holder of a licence under the *Poisons Act 1964*; or

(iii) exempt, or of a class of person who were exempt, under section 9 from such provision or provisions of this Act as are specified in the certificate;

(b) at a date specified in the certificate, there were no exemptions under section 9 applying to goods specified in the certificate;

(c) at the date specified in the certificate, there was no authorisation given by the Commissioner under section 20 applying to goods specified in the certificate; or

(d) at a date specified in the certificate, there was no authorisation given by the Commissioner under section 21 applying to therapeutic devices specified in the certificate.

82. Evidentiary certificates of the Secretary (Cwlth s. 56A)

(1) In any legal proceedings under this Act, a certificate purporting to be signed by the Secretary as to any of the matters set out in subsection (2) is evidence and, in the absence of evidence to the contrary, is proof of the facts stated in the certificate.

(2) The Secretary may certify as to the following —

(a) that at a date specified in the certificate, there were no section 18 exemptions under the Commonwealth Act applying to goods specified in the certificate;

(b) that at a date specified in the certificate, there were no section 19 approvals or authorisations under the Commonwealth Act granted in respect of goods specified in the certificate;

(c) that at a date specified in the certificate, there were no approvals or authorisations under section 8 granted in respect of goods specified in the certificate;

(d) that at a date specified in the certificate, there was no exemption in effect under section 9;

(e) that at a date specified in the certificate, there was no consent given by the Secretary under section 12 applying to goods specified in the certificate;

(f) that at the date specified in the certificate, there were no section 19A exemptions under the Commonwealth Act applying to goods specified in the certificate;

(g) that goods are or are not included in the Register;

(h) specifying the period that goods specified in the certificate were included in the Register, including any conditions applying to the registration or listing of those goods;

(i) that at a date specified in the certificate, the registration or listing of goods specified in the certificate has been cancelled;

(j) that at a date specified in the certificate, no section 7 order under the Commonwealth Act has been issued in respect of goods specified in the certificate;

(k) that at a date specified in the certificate, a licence to manufacture under Part 4 of this Act or the Commonwealth Act has or has not been issued, including any conditions applying to the licence.

83. Provisions relating to evidentiary certificates

(1) A certificate under this section or section 81 or 82 may relate to more than one of the matters referred to in the section.

(2) In proceedings for an offence against section 17, a certificate purported to be signed by the Commissioner to the effect that —

(a) the Commissioner did not approve the supply that is the subject of the proceedings; or

(b) the Commissioner approved that supply subject to the conditions specified in the certificate,

is evidence and, in the absence of evidence to the contrary, is proof of the facts stated in the certificate.

(3) In proceedings for an offence against this Act, a document purporting to be a certificate given under this section or section 81 or 82 is, unless the contrary is proved, taken to be such a certificate and to have been duly given.

84. Conduct by directors, servants and agents (Cwlth s. 55)

(1) Where, in proceedings for an offence against this Act, it is necessary to establish the state of mind of a body corporate in relation to particular conduct, it is sufficient to show —

(a) that the conduct was engaged in by a director, servant or agent of the body corporate within the scope of his or her actual or apparent authority; and

(b) that the director, servant or agent had the state of mind.

(2) Any conduct engaged in or on behalf of a body corporate by a director, servant or agent of the body corporate within the scope of his or her actual or apparent authority is to be taken, for the purposes of a prosecution for an offence against this Act, to have been engaged in also by the body corporate unless the body corporate establishes that the body corporate took reasonable precautions and exercised due diligence to avoid the conduct.

(3) Where, in proceedings for an offence against this Act, it is necessary to establish the state of mind of a person other than a body corporate in relation to particular conduct, it is sufficient to show that —

(a) the conduct was engaged in by a servant or agent of the person within the scope of his or her actual or apparent authority; and

(b) the servant or agent had the state of mind.

(4) Any conduct engaged in on behalf of a person other than a body corporate (in this subsection called the **"employer"**) by a servant or agent of the employer within the scope of his or her actual or apparent authority is to be taken, for the purposes of a prosecution for an offence against this Act, to have been engaged in also by the employer unless the employer establishes

that he or she took reasonable precautions and exercised due diligence to avoid the conduct.

(5) Where —

(a) a person other than a body corporate is convicted of an offence; and

(b) the person would not have been convicted of the offence if subsections (3) and (4) had not been enacted,

the person is not liable to be punished by imprisonment for that offence.

(6) A reference in subsection (1) or (3) to the state of mind of a person includes a reference to —

(a) the knowledge, intention, opinion, belief or purpose of the person; and

(b) the person's reasons for the intention, opinion, belief or purpose.

(7) A reference in this section to a director of a body corporate includes a reference to a constituent member of a body corporate incorporated for a public purpose by a law of the Commonwealth, of a State or of a Territory.

(8) A reference in this section to engaging in conduct includes a reference to failing or refusing to engage in conduct.

85. Judicial notice (Cwlth s. 56)

All courts are to take judicial notice of the British Pharmacopoeia and of the British Pharmacopoeia (Veterinary).

86. Delegation by Secretary (Cwlth s. 57)

(1) The Secretary may by signed instrument delegate the performance of any function of the Secretary under this Act, other than this power of delegation, to any person to whom the

Secretary may delegate any powers under section 57 of the Commonwealth Act.

(2) A delegation may be general or as otherwise provided in the instrument of delegation.

(3) A delegate performing a function under this section is to be taken to do so in accordance with the terms of the delegation unless the contrary is shown.

87. Delegation by Commissioner

(1) The Commissioner may by signed instrument delegate to a person the performance of any function of the Commissioner under this Act other than this power of delegation.

(2) A delegation may be general or as otherwise provided in the instrument of delegation.

(3) A delegate performing a function under this section is to be taken to do so in accordance with the terms of the delegation unless the contrary is shown.

88. Offences under this Act and the Commonwealth Act

If —

(a) an act or omission constitutes an offence under this Act and the Commonwealth Act; and

(b) the offender has been punished for that offence under the Commonwealth Act,

the offender is not liable to be punished for the offence under this Act.

89. Review of decisions (Cwlth s. 60)

(1) In this section —

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

(2) A person —

(a) whose interests are affected by a decision of the Secretary or of a delegate of the Secretary under section 8, section 12, Part 3 or Part 4; and

(b) who is dissatisfied with that decision,

may make an application to the Commonwealth Administrative Appeals Tribunal for review of that decision.

90. Regulations (Cwlth s. 63)

(1) The Governor may make regulations prescribing all matters that are required or permitted by this Act to be prescribed or are necessary or convenient to be prescribed for giving effect to the purposes of this Act.

(2) Without limiting subsection (1), regulations may be made —

(a) prohibiting or regulating the advertising of therapeutic goods, including the form and content of advertisements and the manner in which advertisements may be published or displayed;

(b) with respect to labelling, sampling, examination, testing and analysis of therapeutic goods;

(c) prescribing conditions to be complied with in respect of the preparation, dispensing, storage, packing, handling, carriage and delivery of therapeutic goods;

(d) prohibiting or regulating the supply of therapeutic goods of a specified class or classes;

(e) with respect to the inspection of premises, stocks, books, documents and records;

(f) regulating the circumstances in which therapeutic goods, or therapeutic goods of a specified class or classes, may be supplied by automatic machines, or automatic machines of a particular type or types;

(g) providing for authorisations to be given by the Commissioner for the use of therapeutic devices prohibited under section 21;

(h) prohibiting the supply of therapeutic goods by prescribed self-service methods;

(i) with respect to the unsolicited distribution of therapeutic goods, in accordance with section 17, including the persons who may distribute the goods, the persons, or classes of persons, to whom distribution may be made and the method of distribution;

(j) providing for the disposal of things seized under the Act;

(k) providing that a contravention of a regulation constitutes an offence and prescribing penalties not exceeding $2 000 for any such contravention;

(l) prescribing fees in respect of matters under this Act or the regulations.

(3) The regulations may apply, adopt or incorporate by reference any document formulated or published by a person or body, either —

(a) without modification or as modified by the regulations;

(b) as formulated or published on or before the date when the regulations are made; or

(c) as formulated or published from time to time.

Part 9 — Consequential amendments and transitional provisions

91. ***Health Act 1911 amended***

(1) This section amends the *Health Act 1911**.

(2) Section 3(1) is amended as follows:

(a) by deleting the definitions of "Drug", "the Drug Advisory Committee", "Therapeutic substance", and "Therapeutic use";

(b) in the definition of "Trade description" by deleting "or drug".

(3) Section 5(5) is amended by deleting "and drugs".

(4) Section 5(6) is amended by deleting "or drug" in each place where it occurs.

(5) The heading to Part VIIA is amended by deleting ", drugs, medicines, disinfectants, therapeutic substances".

(6) The provisions specified in the Table to this subsection are repealed.

Table

Section 202	Part VIIA Division 7
Part VIIA Division 5	Section 246D(1)
Part VII Division 6	Section 377(10)

(7) Schedule 5 is amended as follows:

(a) under the heading "*Part I*" by deleting ",225(1), 238(3) and (5)";

(b) under the heading "*Part II*" by deleting ",224(2), 227(13)";

(c) under the heading "*Part IV*" by deleting ",223(1), 225(2), 227(2), 231(2), 234(1) and 240(1)";

(d) under the heading "*Part VI*" by deleting ",221(1), 222, 236(1), 241(1)";

(e) under the heading "*Part VII*" by deleting ",228(2), 237(2), 238(1)".

[* *Reprinted as at 31 March 2000.*]

92. *Health Amendment Act 1987* amended

Sections 4(d), 83 and 90 of the *Health Amendment Act 1987** are repealed.

[* *Act No. 80 of 1987.*]

93. *Health (Drugs and Allied Substances) Regulations 1961* are repealed.

The *Health (Drugs and Allied Substances) Regulations 1961* are repealed.

94. Transitional arrangements for Part 4

(1) This section applies to a step in the manufacture of therapeutic goods in relation to a person in relation to premises in Western Australia if, before the commencement of this section, the person was carrying out that step in relation to goods of that kind at those premises.

(2) Where —

(a) this section applies to a step in the manufacture of therapeutic goods in relation to a person in relation to premises; and

(b) the Secretary is not aware of the person having been convicted of an offence against a law of the

Commonwealth, of a State or of an internal Territory in respect of goods of that kind during the period of 2 years ending on the commencement of this section,

section 48(1) does not apply to the carrying out of that step by the person in relation to goods of that kind at those premises during the period of 4 months after that commencement.

(3) Where —

(a) this section applies to a step in the manufacture of therapeutic goods in relation to a person in relation to premises; and

(b) the person makes an application for a licence to carry out that step in relation to goods of that kind at those premises in accordance with section 49 and within 4 months after the commencement of this section,

section 48(1) does not apply to the carrying out of that step by the person in relation to goods of that kind at those premises until the application is determined.

95. Transitional arrangements for goods required to be registered or listed

(1) This section applies to therapeutic goods in relation to a person if, immediately before the commencement of this section, the person was a sponsor supplying goods of that kind in Western Australia for use in humans.

(2) If —

(a) this section applies to therapeutic goods in relation to a person;

(b) the Secretary is not aware of the person having been convicted of an offence against a law of the Commonwealth, of a State or of an internal Territory in

respect of goods of that kind during the period of 2 years ending on the commencement of this section; and

(c) if the goods are imported goods, the Secretary is not aware of the person having, during that period, imported goods of that kind into Australia otherwise than in accordance with regulations in force under *the Customs Act 1901* of the Commonwealth,

section 15(1) and (3) do not apply to goods of that kind in relation to the person during the period of 4 months after that commencement.

(3) If —

(a) this section applies to therapeutic goods in relation to a person; and

(b) the person makes an application in accordance with section 23 for registration or listing of goods of that kind within 4 months after the commencement of this section,

then —

(c) section 15(1) does not apply to goods of that kind in relation to the person during the period of 6 months after that commencement or before the end of such longer period as the Secretary specifies by notice published in the Commonwealth of Australia Gazette before the end of that 6 month period; and

(d) section 15(3) does not apply to goods of that kind in relation to the person during the period of 12 months after that commencement or before the end of such longer period as the Secretary specifies by notice published in the Commonwealth of Australia Gazette before the end of that 12 month period.

(4) If, on an application referred to in subsection (3), goods have been registered without having been evaluated, the Secretary

may, if he or she thinks it appropriate, give the person in relation to whom the goods are registered written notice that the goods are to be evaluated to determine whether they should continue to be registered.

(5) A person who makes an application referred to in subsection (3) is not required to pay —

(a) any application fee for the registration or listing of the goods to which the application relates; or

(b) in the case of an application for the registration of goods, a fee for the evaluation of the goods for registration,

but, if the goods are later evaluated to determine whether the goods should continue to be registered, a fee that is an amount equal to the fee specified in or determined in accordance with the Commonwealth regulations in relation to an application under section 24 of the Commonwealth Act is payable in respect of that evaluation.

(6) In relation to an evaluation conducted for the purposes of this section —

(a) section 30 has effect as if —

(i) the person in respect of whom the goods are registered were an applicant for the registration of the goods; and

(ii) the reference in subsection (1)(b) to an evaluation fee under section 24 were a reference to a fee payable under subsection (5) of this section;

(b) sections 25, 26 and 27 have effect as if any reference in those sections to section 24 were a reference to subsection (5) of this section; and

(c) sections 28 and 29 do not apply.

(7) If, on an application referred to in subsection (3), goods have been listed without consideration of the matters mentioned in section 33(1)(d) to (k), the Secretary may, if he or she thinks it appropriate, give the person in relation to whom the goods are listed written notice that the Secretary intends to determine whether the goods should continue to be listed.

(8) If notice is given under subsection (7), section 33 applies as if the person in relation to whom the goods are listed were an applicant for the listing of the goods.

Defined Terms

[This is a list of terms defined and the provisions where they are defined. The list is not part of the law.]

Defined Term	Provision(s)
active component	31(3)
advertisement	4(1)
annual licensing charge	4(1)
annual listing charge	4(1)
annual registration charge	4(1)
approved medical practitioner	8(7)
authorised person	4(1)
automatic machine	4(1)
Commissioner	4(1)
Commonwealth Act	4(1)
Commonwealth Department	4(1)
Commonwealth Minister	4(1)
Commonwealth regulations	4(1)
corresponding provision	7(3)
decision	89(1)
employer	84(4)
evidential material	59
exempt goods	4(1)
exempt person	4(1)
first year	57(1)(a)
gazetted kits group	4(1)
gazetted therapeutic devices group	4(1)
gazetted therapeutic goods group	4(1)
grouped therapeutic goods	4(1)
individual patient data	24(3)
licence	4(1)
listable devices	4(1)
listed goods	4(1)
listing number	4(1)
new goods	31(2)
occupier	59
product information	46(7)
protected information	4(1), 31(2)
Register	4(1)
registered goods	4(1)
registration number	4(1)

Defined Terms