Western Australia

Therapeutic Goods (Western Australia) Bill 1999

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Western Australia

LEGISLATIVE ASSEMBLY

(Introduced by Ms McHale, MLA)

Therapeutic Goods (Western Australia) Bill 1999

A Bill for

An Act to make provision for the implementation in Western Australia of controls relating to Western Australian therapeutic goods complementary to the provision made by the Therapeutic Goods Act 1989 of the Commonwealth.

The Parliament of Western Australia enacts as follows:

Part 1 — Preliminary

1. Purpose

The purpose of this Act is 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 for the implementation in Western Australia of controls relating to Western Australian therapeutic goods complementary to the provision made by the *Therapeutic Goods Act 1989* of the Commonwealth.

2. Commencement

(1) Section 1 and this section come into operation on the day on which this Act receives the Royal Assent.

(2) Subject to sub-sections (3) and (4), the remaining provisions of this Act come into operation on a day or days to be proclaimed.

(3) If a provision referred to in sub-section (2) (other than section 16, 17 or Part 5) does not come into operation within the period of 6 months beginning on, and including, the day on which this Act receives the Royal Assent, it comes into operation on the first day after the end of that period.

(4) If section 16, 17 or Part 5 of this Act do not come into operation within the period of 12 months beginning on, and including, the day on which this Act receives the Royal Assent, those provisions come into operation on the first day after the end of that period.

3. Definitions

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 —

(i) a person authorised by the Commissioner of Health or

(ii) an authorised person within the meaning of paragraph (a) of the definition of "authorised person" in the Commonwealth Act; 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;

"British Pharmacopoeia" has the same meaning as in the Commonwealth Act;

"British Pharmacopoeia (Veterinary)" has the same meaning as in the Commonwealth Act;

"Commissioner of Health" means the Commissioner of Health referred to in the *Health Legislation Administration Act 1984*.

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

"Commonwealth Department" means the Department of Human Services and Health 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;

"data processing device" means any article or material (for example, a disc) from which information is capable of being reproduced with or without the aid of any other article or device;

"directions for use", in relation to therapeutic goods, includes information on —

(a) appropriate doses of the goods; and

(b) the method of administration or use of the goods; and

(c) the frequency and duration of treatment for each indication of the goods; and

(d) the use of the goods by persons of particular ages or by persons having particular medical conditions;

"exempt goods" —

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

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

(c) in relation to any provision of this Act, means therapeutic goods that are exempt for the purposes of that provision because of an Order under section 9 of this Act where the goods are used, advertised or

presented for supply in the way specified in the Order;

"exempt person", in relation to therapeutic goods, means —

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

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

"indications", in relation to therapeutic goods, means the specific therapeutic uses of the goods;

"label", in relation to therapeutic goods, means a display of printed information —

(a) on or attached to the goods;

(b) on or attached to a container or primary pack in which the goods are supplied; or

(c) supplied with such a container or pack;

"licence" means a licence under Part 4 or Part 5;

"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 29 of this Act or section 27 of the Commonwealth Act;

"manufacture", in relation to therapeutic goods, means —

(a) to produce the goods; or

(b) to engage in any part of the process of producing the goods or of bringing the goods to their final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or

releasing for supply of the goods or of any component or ingredient of the goods as part of that process;

"manufacturing premises" means premises (including premises that comprise 2 or more sites) —

(a) that are for use in the manufacture of a particular kind of therapeutic goods; and

(b) at which the same persons have control of the management of the production of the goods and the procedures for quality control;

"manufacturing principles" means the principles for the time being having effect under section 36 of the Commonwealth Act;

"premises" includes —

(a) a structure, building, aircraft, vehicle or vessel; and

(b) a place (whether enclosed or built upon or not); and

(c) a part of a thing referred to in paragraph (a) or (b);

"presentation", in relation to therapeutic goods, means the way in which the goods are presented for supply, and includes matters relating to the name of the goods, the labelling and packaging of the goods and any advertising or other informational material associated with the goods;

"primary pack", in relation to therapeutic goods, means the complete pack in which the goods, or the goods and their container, are to be supplied to consumers;

"quality", in relation to therapeutic goods, includes the composition, strength, potency, stability, sterility, purity, bioburden, design, construction and performance characteristics of the goods;

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

"registered goods" means therapeutic goods 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 29 of this Act or under section 27 of the Commonwealth 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; and

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

(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; or

(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 sub-paragraph (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; or

(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; or

(e) foods;

"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; or

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

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

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

(e) testing for pregnancy in persons; or

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

4. Definitions in Commonwealth Act

(1) Words and expressions used in the Commonwealth Act and in this Act have the same meanings in this Act as they have in the Commonwealth Act.

(2) Subsection (1) does not apply to the extent that the context or subject-matter otherwise indicates or requires.

5. Interpretation

(1) 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.

(2) The Commissioner of Health must, at least once in each year, cause to be published in the *Government Gazette* a list of the names of all persons who are, at the time of publication, persons authorised by the Commissioner of Health as authorised persons for the purposes of this Act.

(3) The provisions of this Act are in addition to, and not in substitution for, the provisions of any other Act that relate to therapeutic goods.

(4) 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; or

(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; or

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

(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.

6. Act to bind Crown

This Act binds the Crown not only in right of Western Australia but also, so far as the legislative power of the Parliament permits, the Crown in all its other capacities.

7. Authorised persons

The Commissioner of Health may, in writing, authorise any of the following persons to exercise powers under a specified provision of this Act —

(a) an employee in the public service;

(b) an officer of the Commonwealth Department or of another Department of the Commonwealth or of an authority of the Commonwealth, being a Department or authority that has functions relating to health matters or law enforcement matters.

8. Secretary may approve or authorise the supply of certain therapeutic goods

(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; and

(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 registered medical practitioner 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 sub-section (5) does not render 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 *Government 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 subsection (1) is subject to such conditions, if any, as are specified in the Order.

10. Kits

(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; and

(b) each item of the therapeutic goods consists of goods that are registered or listed or are exempt goods in relation to 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; and

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

(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

(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 this section.

(4) A person must not, in purported compliance with a notice under this section, knowingly or recklessly provide information that is false or misleading in a material particular.

Penalty: $6 000.

Part 2 — Standards

12. Compliance with standards

(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: $24 000.

(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.

(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) Where a person breaches a condition of such a consent, the person is guilty of an offence.

Penalty: $12 000.

Part 3 — Australian Register of Therapeutic Goods

Division 1 — Preliminary

14. Offences by sponsors

(1) A person who is the sponsor of therapeutic goods must not knowingly or recklessly —

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

(b) supply the goods in Western Australia for use in humans,

unless —

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

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

Penalty: $24 000.

(2) A person in relation to whom therapeutic goods are registered or listed must not knowingly or recklessly 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: $6 000.

15. Offence relating to supply of unregistered or unlisted goods

A person must not knowingly or recklessly 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; or

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

Penalty: $12 000.

16. Hawking of therapeutic goods

(1) A person must not, without the written consent of the Commissioner of Health, supply therapeutic goods in a street or from house to house.

Penalty: $1 000.

(2) Subsection (1) does not apply to the supply by free distribution of clinical samples of therapeutic goods to a registered medical practitioner, pharmacist, dentist or veterinary practitioner if —

(a) the supply is by a person licensed to manufacture or supply by wholesale therapeutic goods; and

(b) the goods are supplied to the registered medical practitioner, pharmacist, dentist or veterinary practitioner personally or by post in a letter or parcel addressed to him or her.

17. Supply by vending machine

(1) A person must not, without the written consent of the Commissioner of Health, whether in premises under his or her control or elsewhere —

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

(b) supply therapeutic goods by means of a vending machine.

Penalty: $1 000.

(2) A person must not, without the written consent of the Commissioner of Health, permit a vending machine for the supply of therapeutic goods to be installed on premises owned or occupied by him or her.

Penalty: $1 000.

(3) A person must not, without the written consent of the Commissioner of Health, permit therapeutic goods to be placed in a vending machine under his or her control.

Penalty: $1 000.

18. General offences relating to this Part

(1) A person must not knowingly or recklessly 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.

(2) A person must not, in or in connection with an application for listing of therapeutic goods, knowingly or recklessly make a statement that is false or misleading in a material particular.

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

(4) A person must not knowingly or recklessly —

(a) represent therapeutic goods that are not included in the Register as being so included; or

(b) represent therapeutic goods that are not exempt goods as being exempt goods; or

(c) represent therapeutic goods that are included in one part of the Register as being included in the other part of the Register.

(5) A person, being the sponsor of therapeutic goods that are included in the Register, must not, by any means, knowingly or

recklessly advertise the goods for an indication other than those accepted in relation to the inclusion of the goods in the Register.

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

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

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

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

(c) an approval under section 8; or

(d) an exemption under section 9.

(8) A person to whom an authority under section 19(5) of the Commonwealth Act or under section 8 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 knowingly or recklessly use 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,

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

Penalty: $6 000.

19. False statements in applications for registration

A person must not, in or in connection with an application for registration of therapeutic goods, knowingly or recklessly make a statement that is false or misleading in a material particular.

Penalty: $40 000.

Division 2 — Registration and Listing

20. Applications generally

(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 application fee prescribed under the Commonwealth regulations in respect of an application under section 23 of the Commonwealth Act has been paid; and

(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.

21. Applications for registration

(1) Where an application is made for the registration of therapeutic goods in accordance with section 20 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 25, 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; or

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

(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 35, is inaccurate or misleading in a material particular; or

(d) the applicant fails to comply with a requirement under section 35 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.

22. When evaluation fee due for payment

Subject to sections 23 and 25, an evaluation fee under section 21 payable by an applicant is due and payable on the day on which the applicant is notified of the amount of the evaluation fee.

23. Payment of evaluation fee by instalments

(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 21 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 21 in circumstances of that kind by instalments.

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

24. Recovery of evaluation fee

An evaluation fee under section 21 may be recovered by the Commonwealth as a debt due to the Commonwealth.

25. Reduction of evaluation fee where evaluation not completed within prescribed period

(1) This section applies to an application under section 20 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 21, 22 or 23 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 under section 21 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 27(5) of the Secretary's decision on the application.

26. Deemed refusal of application

(1) This section applies in the case of an application under section 20 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, at the end of the period referred to in subsection (1), the evaluation has not been completed, 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.

27. Evaluation of therapeutic goods

(1) Where —

(a) an application is made for the registration of therapeutic goods in relation to a person in accordance with section 20; and

(b) there is no part of an evaluation fee under section 21 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 35 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; and

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

(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; and

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

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

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

(2) 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.

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

(4) If a person is exempt from the operation of Part 4 of the Commonwealth 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 (g) to Part 4 were a reference to that Part to the extent that it applies to that person in relation to the manufacture of the goods.

(5) 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.

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

28. Listing of therapeutic goods

(1) Where —

(a) an application is made for the listing of therapeutic goods in relation to a person in accordance with section 20; and

(b) the person has complied with any requirements made by the Secretary under section 35 in relation to the goods,

the Secretary must not refuse to list the goods in relation to the person unless the Secretary is satisfied that —

(c) the goods are not eligible for listing; or

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

(e) the presentation of the goods is unacceptable; or

(f) 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

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

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

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

(2) If therapeutic goods are exempt from the operation of Part 4 of the Commonwealth Act or a person is exempt from the operation of that Part in relation to the manufacture of the goods, sub-section (1) has effect, in relation to the goods, as if paragraph (g) were omitted.

(3) If a person is exempt from the operation of Part 4 of the Commonwealth 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 (g) to Part 4 were a reference to that Part to the extent that it applies to that person in relation to the manufacture of the goods.

(4) 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.

(5) 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.

29. Registration or listing number

(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.

30. Conditions on registration or listing

(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; or

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

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

(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.

31. Duration of registration or listing

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.

32. Notification of adverse effects etc. of goods

(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.

33. Notification of adverse effects etc. where application withdrawn or lapses

(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 32(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.

Penalty: $40 000.

(4) A person must not, in purported compliance with a notice under subsection (1), knowingly or recklessly give information that is false or misleading in a material particular.

Penalty: $40 000.

34. Cancellation of registration or listing

(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; or

(b) the goods become exempt goods; or

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

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

(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; or

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

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

(d) the person has contravened section 32(1) in relation to the goods; or

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

(f) 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

(g) 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) 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.

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

(a) may, in writing, require the person —

(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; or

(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.

(7) A person who knowingly or recklessly refuses or fails to comply with a requirement under subsection (6)(a) is guilty of an offence.

Penalty: $6 000.

Division 3 — General

35. Secretary may require information

(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, 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 manufacture 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;

(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) An approval of a form may require or permit 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.

(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: $6 000.

(5) A person in relation to whom therapeutic goods are registered or listed must not, in purported compliance with a notice under this section, knowingly or recklessly provide information that is false or misleading in a material particular.

Penalty: $6 000.

36. Inspection and variation of entries in Register

(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 and, where such a request is made, the Secretary must send a copy of that entry to a person (other than any part of that entry that was supplied in confidence by another person).

(2) If a 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.

(3) 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.

(4) 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.

(5) 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; and

(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.

(6) In this section, "product information", in relation to therapeutic goods, means information relating to the safety and effective use of the goods, including information regarding the usefulness and limitations of the goods.

37. Publication of list of goods on Register

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

38. Offences relating to manufacturing and licences

(1) A person must not, at premises in Western Australia, knowingly or recklessly 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: $24 000.

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

Penalty: $12 000.

(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, to the person's knowledge, false or misleading in a material particular.

Penalty: $6 000.

39. Application for licence

(1) An application for a licence must —

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

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

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

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

(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; and

(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.

40. Grant of licence

(1) Where —

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

(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; and

(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 39(2) 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; or

(f) the person —

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

(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; or

(iii) 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 sub-section (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.

41. Term of licence

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

42. Conditions of licences

(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; and

(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; and

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

(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.

43. Revocation and suspension of licences

(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; or

(b) the holder has breached a condition of the licence; or

(c) the holder has failed to observe the manufacturing principles; or

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

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

(f) 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 of suspension of the licence before taking into account the submissions.

(4) A licence may be revoked notwithstanding that 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.

44. Publication of list of manufacturers etc.

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 — Licences to Supply by Wholesale

45. Definition and application of Part

(1) In this Part, "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.

(2) Nothing in this Part affects the operation of any other Part in relation to the supply of therapeutic goods.

46. Offences relating to supply by wholesale and licences

(1) A person must not, in Western Australia, supply by wholesale therapeutic goods for use in humans unless —

(a) the person is the holder of a licence under this Part that authorises supply by wholesale of the goods; or

(b) the therapeutic goods are exempt goods for the purposes of Parts 3 or 4 or under section 9 or the person is an exempt person in relation to supply by wholesale of those goods; or

(c) the person is licensed under section 35 of the Commonwealth Act in respect of the goods or class of goods described in that licence; or

(d) the person is the holder of a licence granted under section 24 of the *Poisons Act 1964* and prescribed by regulation for the purposes of this subsection; or

(e) the supply by the person is a supply by wholesale that is authorised under the *Poisons Act 1964* and is to be

regarded as a sale or supply in the lawful practice of that person's profession as a pharmacist.

Penalty: $10 000.

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

Penalty: $10 000.

(3) A person must not, in or in connection with an application for a licence to supply by wholesale therapeutic goods for use in humans, make a statement that is, to the person's knowledge, false or misleading in a material particular.

Penalty: $ 6 000.

(4) In this section, "therapeutic goods" does not include therapeutic devices unless they are prescribed by the regulations as therapeutic goods to which this section applies.

47. Application for licence

(1) An application for a licence to supply by wholesale must —

(a) be made in writing to the Commissioner of Health in accordance with a form approved by the Commissioner of Health; and

(b) identify the therapeutic goods or classes of therapeutic goods that the applicant proposes to supply by wholesale; and

(c) identify the premises that will be used in the storage, handling and supply of those goods; and

(d) identify the measures proposed for the control of the storage, handling and supply of the goods and the stock control measures that are to be employed; and

(e) be accompanied by the prescribed application fee.

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

(a) to give to the Commissioner of Health, 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 proposed to be used by the applicant in the course of the business of supply by wholesale of therapeutic goods.

48. Grant of licence

(1) Where —

(a) a person has made an application for a licence to supply therapeutic goods by wholesale; and

(b) the prescribed application fee has been paid; and

(c) any applicable prescribed inspection fees in respect of the grant of a licence have been paid; and

(d) the person has complied with any requirements made by the Commissioner of Health under section 47(2) in relation to the application,

the Commissioner of Health must grant the person a licence to supply by wholesale therapeutic goods of the class specified in the licence if satisfied —

(e) that the premises are satisfactory for the handling, storage or supply of goods of that class; and

(f) as to the matters referred to in section 47(1)(d); and

(g) the person —

(i) has not been the holder of a licence granted under this Act or the Commonwealth Act that has been revoked; and

(ii) has not been convicted of an offence against this Act, the Commonwealth Act or a law of another State or Territory relating to therapeutic goods.

(2) The Commissioner of Health may grant a licence to a person who could not be granted a licence because the person —

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

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

if, in the opinion of the Commissioner of Health, special circumstances make it appropriate to do so.

(3) Where the Commissioner of Health grants or refuses to grant a licence to a person, the Commissioner of Health 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.

49. Term of licence

A licence commences on the day specified in the licence and remains in force for 12 months from that date.

50. Renewal of licence

(1) An application for renewal of a licence —

(a) may be made up to one month before the expiry of the current licence; and

(b) must be made in writing and be accompanied by the prescribed renewal fee.

(2) Subject to this Act and the regulations, on application under subsection (1), the Commissioner of Health, in his or her discretion, may renew the licence.

(3) A renewed licence remains in force for 12 months from the expiry of the previous licence.

51. Conditions of licences

(1) A licence may be granted subject to —

(a) conditions designed to ensure that the holder of the licence supplies the therapeutic goods of the class specified in the licence in accordance with appropriate prescribed standards of hygiene, storage, handling and monitoring controls applicable to goods of that class; and

(b) such other conditions relating to supply by wholesale of goods of that class as the Commissioner of Health thinks appropriate.

(2) The Commissioner of Health 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 goods of the class specified in the licence conform to any standard applicable to goods of that class; and

(b) allow an authorised person —

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

(ii) while on those premises, to inspect those premises, any therapeutic goods handled, stored at or supplied from those premises and processes relating to that supply, 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; and

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

(d) if requested to do so by an authorised person, produce to the person such documents relating to the handling, storage or supply of therapeutic goods at those premises as the person requires and allow the person to copy the documents; and

(e) comply with the prescribed conditions (if any).

52. Revocation and suspension of licences

(1) Subject to subsection (2), the Commissioner of Health 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; or

(b) the holder has breached a condition of the licence; or

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

(d) the holder ceases to carry on the business of supplying by wholesale the goods to which the licence relates; or

(e) the prescribed licence renewal fee and any applicable prescribed inspection fees, have not been paid within 28 days after they become payable.

(2) Where the Commissioner of Health proposes to revoke a licence or suspend a licence otherwise than at the request of the holder of the licence, the Commissioner of Health must, unless the Commissioner of Health 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 Commissioner of Health 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 prescribed licence renewal fee or an applicable prescribed inspection fee, give the holder an opportunity to make, within such reasonable time as is specified in the notice, submissions to the Commissioner of Health in relation to the proposed action.

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

(4) A licence may be revoked notwithstanding that the licence is suspended.

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

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

53. Publication of list of wholesale suppliers

The Commissioner of Health may, from time to time and in such manner as the Commissioner of Health determines, publish a list of the persons who are licensed under this Part, the classes of goods to which the licences relate and the addresses of the premises to which the licences relate.

Part 6 — Payment of Charges

54. By whom charges payable

(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.

55. Time for payment of charges

(1) An annual registration charge or annual listing charge for a financial year relating to therapeutic goods other than grouped therapeutic goods is payable on the day of the commencement of the registration or listing of the therapeutic goods and on each anniversary of that day.

(2) An annual registration charge or annual listing charge for a financial year relating to grouped therapeutic goods is 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 is 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.

(5) In this section, "grouped therapeutic goods" has the same meaning as in the Commonwealth Act.

56. 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 — Miscellaneous

57. Monitoring compliance with Act

(1) Subject to subsection (2), an authorised person may, for the purpose of finding out whether the requirements of this Act are being complied with —

(a) enter premises; and

(b) exercise the powers set out in section 59(1) in relation to the premises.

(2) An authorised person must not enter premises, or exercise a power under subsection (1) in relation to the premises, unless —

(a) the occupier of the premises consents to the entry or the exercise of the power; or

(b) a warrant under section 60 authorises the entry or the exercise of the power.

58. Entry and search of premises—evidence of offences

(1) Subject to subsection (3), if an authorised person has reasonable grounds for suspecting that there is in or on premises a particular thing (in this section called the "evidence") that may afford evidence of the commission of an offence against this Act, the authorised person may —

(a) enter the premises; and

(b) exercise the powers set out in section 59(1) in relation to the premises.

(2) If the authorised person enters the premises and finds the evidence, the following provisions have effect —

(a) the authorised person may seize the evidence;

(b) the authorised person may keep the evidence for 90 days or, if a prosecution for an offence against this Act in the commission of which the evidence may have been used or otherwise involved is instituted within that period,

until the completion of the proceedings for the offence and of any appeal from the decision in relation to the proceedings;

(c) if the evidence is a book, record or document, while the authorised person has possession of the book, record or document, the authorised person must allow the book, record or document to be inspected at any reasonable time by a person who would be entitled to inspect it if it were not in the authorised person's possession.

(3) The authorised person must not enter the premises, or exercise a power in relation to the premises under subsection (1), unless —

(a) the occupier of the premises consents to the entry or the exercise of the power; or

(b) a warrant under section 61 issued in relation to the evidence authorises the entry or the exercise of the power.

(4) If, in the course of searching the premises under subsection (1) pursuant to a warrant under section 61, the authorised person —

(a) finds a thing that the authorised person believes, on reasonable grounds, to be a thing (other than the evidence) that will afford evidence of the commission of the offence mentioned in subsection (1) or of another offence against this Act; and

(b) believes, on reasonable grounds, that it is necessary to seize the thing to prevent —

(i) its concealment, loss or destruction; or

(ii) its use in committing, continuing or repeating the offence mentioned in subsection (1) or the other offence,

subsection (2) applies to the thing as if it were the evidence.

(5) An authorised person may, before the end of the period mentioned in subsection (2)(b), apply to a magistrate for an extension of that period.

(6) A person who would be entitled to possession of the evidence if it had not been seized is entitled to make representations to the magistrate about the application.

(7) The magistrate may extend the period if satisfied that it is necessary to do so in order that an authorised person may have a reasonable opportunity of completing the investigation of an offence against this Act.

(8) The period may not be extended —

(a) after it has ended; or

(b) so that it exceeds 3 years.

(9) Where the period referred to in subsection (2)(b) has been extended, a reference in subsection (5), (7) or (8) to that period is a reference to that period as extended.

59. General powers of authorised persons in relation to premises

(1) The powers an authorised person may exercise under section 57(1)(b) or 58(1)(b) in relation to premises are as follows —

(a) to search any part of the premises;

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

(c) to take extracts from, and make copies of, any documents relating to therapeutic goods in or 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 books, records or documents requested by the authorised person; and

(e) if the authorised person was authorised to enter the premises by a warrant under section 60 or 61, to require any person in or on the premises to —

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

(ii) produce any books, records or documents requested by the authorised person;

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

(2) Subsection (1) has effect subject to sections 57(2) and 58(3).

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

Penalty: $3 000.

(4) 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.

60. Monitoring warrants

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

(2) Subject to subsection (3), the magistrate may issue the warrant if the magistrate satisfied, by information on oath, that it is reasonably necessary that the authorised person should have

access to the premises for the purpose of finding out whether the requirements of this Act are being complied with.

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

(4) The warrant must —

(a) authorise an authorised person (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 59(1) in relation to the premises; and

(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; and

(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.

61. Offence related warrants

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

(2) Subject to subsection (3), the magistrate may issue the warrant if the magistrate is 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 a particular thing (in this section called the "evidence") that may afford evidence of the commission of an offence against this Act.

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

(4) The warrant must —

(a) state the name of the authorised person; and

(b) authorise the authorised person, 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 59(1); and

(iii) to seize the evidence; and

(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; and

(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.

62. Identity cards

(1) The Commissioner of Health 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 an authorised person referred to in subsection (1) enters premises otherwise than under a warrant, the authorised person must, if requested to do so by any person at those premises, produce his or her identity card for inspection by that person.

(3) 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 of Health.

Penalty: $100.

63. Offences

(1) An offence against section 19, 32, or 33 is an indictable offence.

(2) 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.

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

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

(5) A prosecution in respect of an indictable offence against this Act may be commenced at any time within 3 years after the commission of the offence.

64. Evidentiary certificate of Commissioner of Health

In any legal proceedings under this Act, a certificate purporting to be signed by the Commissioner of Health stating that a person was or was not, at a date specified in the certificate —

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

(b) the holder of a licence under section 24 of the *Poisons Act 1964*; or

(c) a person to whom, in his or her profession as a pharmacist, an authorisation under the *Poisons Act 1964* applied,

is evidence, and in the absence of evidence to the contrary, is proof of the facts stated in the certificate.

65. Evidentiary certificates of the Secretary

(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 are no section 18 exemptions under the Commonwealth Act applying to goods;

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

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

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

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

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

(g) 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.

66. Conduct by directors, servants and agents

(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.

67. Judicial notice

All courts are to take judicial notice of the British Pharmacopoeia and of the British Pharmacopoeia (Veterinary).

68. Delegation

The Secretary may delegate any of his or her powers under this Act, other than this power of delegation, to a person to whom the Secretary may, under section 57 of the Commonwealth Act, delegate any of his or her powers under that Act.

69. 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.

70. Review of decisions excluding decisions under Part 5

(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.

71. Review by Supreme Court

(1) A person whose interests are affected by a decision of the Commissioner of Health under Part 5 may apply to the Supreme Court for review of the decision.

(2) An application for review must be made within 28 days after the day on which the decision is made.

72. Regulations

(1) The Governor may make regulations for or with respect to —

(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) labelling, sampling, examination, testing and analysis of therapeutic goods;

(c) 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) fees payable under Part 5;

(f) the inspection of premises, stocks, books, documents and records;

(g) prohibiting the supply of therapeutic goods by prescribed self-service methods;

(h) providing for the disposal of things seized under the Act;

(i) prescribing penalties not exceeding $2 000 for any contravention of the regulations;

(j) any other matter or thing required or permitted by this Act to be prescribed or necessary to be prescribed to give effect to this Act.

(2) The regulations may —

(a) be of general or limited application;

(b) differ according to differences in time, place or circumstance;

(c) apply, adopt or incorporate by reference any document formulated or published by a person or body, either —

(i) without modification or as modified by the regulations; or

(ii) as formulated or published on or before the date when the regulations are made; or

(iii) as formulated or published from time to time;

(d) confer a discretionary authority or impose a duty on a specified person or class of persons.

Part 8 — Consequential Amendments and Transitional Provisions

73. Amendments to the *Health Act 1911*

(1) Section 3 of the *Health Act 1911* is amended in the definition of "drug" by inserting after "includes" the following —

"

a drug that is a listed or registered therapeutic good within the meaning of the *Therapeutic Goods Act (Western Australia) 1999* or the Therapeutic Goods Act 1989 of the Commonwealth,

".

(2) Section 223 of the *Health Act 1911* is amended by inserting after subsection (2) the following —

"

(3) In any prosecution under subsection (1)(a) it shall be a good defence that the therapeutic substance is a listed or registered therapeutic good within the meaning of the *Therapeutic Goods Act (Western Australia) 1999* or the Therapeutic Goods Act 1989 of the Commonwealth.

".

(3) Division 7 of Part VIIA of the *Health Act 1911* is repealed.

74. Amendments to the *Poisons Act 1964*

Section 6(1) of the *Poisons Act 1964* is amended by inserting after "*Misuse of Drugs Act 1981*" the following —

" and the *Therapeutic Goods Act 1999* ".

75. 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 38(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 39 and within 4 months after the commencement of this section,

section 38(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.

76. Transitional arrangements for Part 5

(1) Section 46(1) does not apply to the supply by wholesale of therapeutic goods by a person who, during the whole period of 6 months before the commencement of this section, was engaged in the supply by wholesale of therapeutic goods of that kind.

(2) A person to whom subsection (1) applies may make application for a licence to supply by wholesale therapeutic goods in accordance with section 47 and, if the person makes an application within 6 months after the commencement of this section, section 46(1) does not apply to the supply by wholesale of therapeutic goods of that kind by that person until the application is determined.

77. 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; 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; 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,

sections 14(1) and (2) do not apply to goods of that kind in relation to the person during the period of 3 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 20 for registration or listing of goods of that kind within 3 months after the commencement of this section,

then —

(c) section 14(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 14(2) 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 under 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 in accordance with 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 27 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 21 were a reference to a fee payable under subsection (5) of this section; and

(b) sections 22, 23 and 24 have effect as if any reference in those sections to section 21 were a reference to sub-section (5) of this section; and

(c) sections 25 and 26 do not apply.

(7) If, on an application under subsection (3), goods have been listed without consideration of the matters mentioned in section 28(1)(c) to (i), 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 28 applies as if the person in relation to whom the goods are listed were an applicant for the listing of the goods.