



Therapeutic Goods Act 1989

No. 21 of 1990

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SCHEDULE



Therapeutic Goods Act 1989

No. 21 of 1990

An Act relating to therapeutic goods

[Assented to 17 January 1990]

BE IT ENACTED by the Queen, and the Senate and the House of Representatives of the Commonwealth of Australia, as follows:

PART 1—PRELIMINARY

Short title

1. This Act may be cited as the *Therapeutic Goods Act 1989*.

Commencement

2. This Act commences on the day after the day on which a House of the Parliament approves regulations made under this Act in the same form as approved by the other House, provided that:

- (a) not more than 90 days have elapsed; and
- (b) the places of Senators have not become vacant under section 13 of the Constitution; and
- (c) a dissolution or expiration of the House of Representatives has not occurred,

between the approval of one House and the approval of the other House.

Interpretation

3. (1) In this Act, unless the contrary intention appears:

“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;

“authorised person”, in relation to a provision of this Act, means:

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

(b) an officer of:

(i) a Department of State of a State; or

(ii) a Department or administrative unit of the Public Service of a Territory; or

(iii) an authority of a State or of a Territory;

being a Department, unit or authority that has functions relating to health matters; or

(c) a member of the Australian Federal Police;

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

“batch” means a quantity of a product that is:

(a) uniform in composition, method of manufacture and probability of chemical or microbial contamination; and

(b) made in one cycle of manufacture and, in the case of a product that is sterilised or freeze dried, sterilised or freeze dried in one cycle;

“bioburden”, in relation to therapeutic goods, means the quantity and characteristics of microorganisms present in the goods or to which the goods may be exposed in a manufacturing environment;

“British Pharmacopoeia” means the edition of the book of that name, including any additions or amendments, that was in effect for the purposes of the *Therapeutic Goods Act 1966* immediately before the commencement of this section and, if additions or amendments of that book are made after that commencement, or new editions of that book are published after that commencement, includes those additions or amendments, or those new editions, from a day specified by the Minister by order published in the *Gazette*;

“British Pharmacopoeia (Veterinary)” means the latest edition of the book of that name, including any additions or amendments, published on the recommendation of the Medicines Commission of the United Kingdom immediately before the commencement of this section and, if additions or amendments of that book are made after that commencement, or new editions of that book are published after that commencement, includes those additions or amendments, or those new editions, from a day specified by the Minister by order published in the *Gazette*;

- “container”**, in relation to therapeutic goods, means the vessel, bottle, tube, ampoule, syringe, vial, sachet, strip pack, blister pack, wrapper, cover or other similar article that immediately covers the goods, but does not include an article intended for ingestion;
- “corporation”** means a body corporate that is:
- (a) a foreign corporation; or
 - (b) a trading corporation formed within the limits of the Commonwealth or a financial corporation so formed;
- “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”**, in relation to a provision of Part 3 or 4, means therapeutic goods that are exempted from the operation of that Part by the regulations;
- “exempt person”**, in relation to therapeutic goods, means a person exempted from the operation of Part 4 in relation to those goods by the regulations;
- “financial corporation”** means a financial corporation within the meaning of paragraph 51 (xx) of the Constitution;
- “foreign corporation”** means a foreign corporation within the meaning of paragraph 51 (xx) of the Constitution;
- “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; or
 - (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;
- “listable devices”** means therapeutic devices that are required to be included in the part of the Register for listed goods;
- “listed goods”** means therapeutic goods that are included in the part of the Register for goods known as listed goods;
- “listing number”**, in relation to listed goods, means any combination of numbers, symbols and letters assigned to the goods under section 27;
- “manufacture”**, in relation to therapeutic goods, means:
- (a) to produce the goods; or

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- (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 sale of the goods or of any component or ingredient of the goods as part of that process;

“manufacturing premises” means a building, a part of a building or a group of buildings on one or more sites:

- (a) that is 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;

“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;

“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 27;

“Secretary” means the Secretary to the Department;

“sponsor”, in relation to therapeutic goods, means a person who:

- (a) exports, or arranges the export of, the goods from Australia; or
- (b) imports, or arranges the importation of, the goods into Australia; or

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- (c) in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere);

but does not include a person who exports, imports or manufactures goods on behalf of another person;

“standard”, in relation to therapeutic goods, means a standard that:

- (a) is specified in an order under section 10 that is applicable to the goods; or
- (b) if no such order is 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 devices” means therapeutic goods other than goods that are represented to achieve, or are likely to be taken to achieve, any of the principal purposes of their use as a result of chemical action within or upon the body of a person or animal, but does not include therapeutic goods declared by the Secretary, by order published in the *Gazette*, 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 subparagraph (i) or (ii); or
- (b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a) (ii) or (iii);

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and includes goods declared to be therapeutic goods under an order in force under section 7, but does not include:

- (c) goods declared not to be therapeutic goods under an order in force under section 7; 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 or labelled in the way specified in the order where the goods are used or labelled 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;

and includes use in, or in connection with, contraception or testing for pregnancy;

“trading corporation” means a trading corporation within the meaning of paragraph 51 (xx) of the Constitution.

(2) For the purposes of this Act:

- (a) therapeutic goods are to be taken to be for use in animals if:
 - (i) the goods bear a name or description that indicates, or is likely to give the impression, that the goods are intended for use in animals and are not intended for use in humans; or
 - (ii) the goods are otherwise represented, or otherwise purport, to be intended for use in animals and not intended for use in humans; and
- (b) therapeutic goods are to be taken to be for use in humans if they are not solely for use in animals.

(3) The Secretary must, at least once in each year, cause to be published in the *Gazette* a list of the names of all persons who are, at the time of publication, authorised persons.

(4) 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.

(5) 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 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 Australia; or
- (e) in prescribed cases.

(6) A reference in this Act to an annual registration charge, an annual listing charge or an annual licensing charge is a reference to such a charge imposed under the *Therapeutic Goods (Charges) Act 1989*.

Object of Act

4. The object of this Act is to provide, so far as the Constitution permits, for the establishment and maintenance of a national system of controls relating to the quality, safety and efficacy of therapeutic goods that:

- (a) are used in Australia, whether those goods are produced in Australia or elsewhere; or
- (b) are exported from Australia.

Act to bind Crown

5. This Act binds the Crown in right of the Commonwealth, of each of the States, of the Australian Capital Territory and of the Northern Territory, but nothing in this Act renders the Crown liable to be prosecuted for an offence.

Operation of Act

6. (1) This Act applies to:

- (a) things done by corporations; and
- (b) things done by natural persons or corporations in so far as those things are done:
 - (i) in the course of, or in preparation for, trade or commerce between Australia and a place outside Australia, among the States, between a State and a Territory or between 2 Territories; or
 - (ii) under a law of the Commonwealth relating to the provision of pharmaceutical or repatriation benefits; or
 - (iii) in relation to the Commonwealth or in relation to an authority of the Commonwealth.

(2) Without limiting the effect of this Act apart from this subsection, this Act also has the effect it would have if the reference in paragraph (1) (a) to things done by corporations were confined to things done by trading corporations for the purposes of their trading activities.

(3) The provisions of this Act are intended to apply to the exclusion of any law of a State or Territory, other than laws identified in the regulations for the purposes of this subsection.

Goods may be declared to be or not to be therapeutic goods

7. (1) Where the Secretary is satisfied that particular goods or classes of goods:

- (a) are or are not therapeutic goods; or
- (b) when used or labelled in a particular way, are or are not therapeutic goods;

the Secretary may, by order published in the *Gazette*, declare that the goods, or the goods when used or labelled in that way, are or are not, for the purposes of this Act, therapeutic goods.

(2) The Secretary may exercise his or her powers under this section of his or her own motion or following an application made in writing to the Secretary.

(3) A declaration under this section takes effect on the day on which the declaration is published in the *Gazette* or on such later day as is specified in the notice.

Power to obtain information with respect to therapeutic goods

8. (1) The Secretary may, by notice in writing given to a person who has imported into Australia or has supplied in Australia:

- (a) therapeutic goods; or
- (b) goods in relation to which the Secretary is considering making a declaration under section 7;

request the person to give to an officer of the Department identified in the notice, within such reasonable period as is specified in the notice, information in writing 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 person must not, without reasonable excuse, fail to comply with a notice given to the person under this section.

(3) 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.

Arrangements with States etc.

9. (1) The Minister may make arrangements with the appropriate Minister of a State, of the Australian Capital Territory or of the Northern Territory for the carrying out by that State or Territory, on behalf of the Commonwealth, of:

- (a) the evaluation of therapeutic goods for registration; or

- (b) the inspection of manufacturers of therapeutic goods; or
- (c) other functions under this Act or the regulations.

(2) An arrangement under this section may provide for the payment to a State or Territory of amounts in respect of the performance of functions under the arrangement.

PART 2—STANDARDS

Determination of standards

10. (1) The Minister may, by order published in the *Gazette*, determine that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order (whether or not those goods are the subject of a monograph in the British Pharmacopoeia or the British Pharmacopoeia (Veterinary)).

(2) Without limiting the generality of subsection (1), an order establishing a standard for therapeutic goods may:

- (a) be specified by reference to:
 - (i) the quality of the goods; or
 - (ii) the quantity of the goods when contained in specified containers; or
 - (iii) procedures to be carried out in the manufacture of the goods; or
 - (iv) a monograph in the British Pharmacopoeia or the British Pharmacopoeia (Veterinary); or
 - (v) a monograph in another publication approved by the Minister for the purposes of this subsection; or
 - (vi) such a monograph as modified in a manner specified in the order establishing the standard; or
 - (vii) a standard published by the Standards Association of Australia; or
 - (viii) such other matters as the Minister thinks fit; or
- (b) require that a matter relating to the standard be determined in accordance with a particular test; or
- (c) require that therapeutic goods or a class of therapeutic goods identified in the order be labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the order.

(3) Without limiting the generality of paragraph (2) (c), the Minister may, in an order establishing a standard, direct that there be set out, in a manner specified in the order, on:

- (a) therapeutic goods or a class of therapeutic goods identified in the order; or
- (b) a container or package containing therapeutic goods or a class of therapeutic goods identified in the order; or

- (c) a label of therapeutic goods or a class of therapeutic goods identified in the order;

such particulars as are required by the order.

(4) The Minister must not determine a standard or amend or revoke a standard unless the Minister has consulted with respect to the proposed action with a committee established by the regulations to advise the Minister on standards.

Date of effect of standards

11. A standard under section 10 takes effect on the day on which the order establishing the standard is published in the *Gazette* or on such later day as is specified in the order.

Standards to be disallowable

12. Standards under section 10 and orders revoking, varying or modifying standards of that kind are disallowable instruments for the purposes of section 46A of the *Acts Interpretation Act 1901*.

Special provisions relating to standards

13. (1) Unless the contrary intention appears in a standard, the standard applies to therapeutic goods for use in humans and therapeutic goods for use in animals.

(2) For the purposes of this Part, where a statement in a monograph in the *British Pharmacopoeia* or the *British Pharmacopoeia (Veterinary)* refers to a statement in a monograph in another publication, the first-mentioned statement is to be taken to include the other statement.

(3) Subject to subsection (4), where:

- (a) a standard applicable to therapeutic goods is constituted by statements in a monograph in the *British Pharmacopoeia* or the *British Pharmacopoeia (Veterinary)*; and
- (b) requirements applicable to the labelling or packaging of the goods are specified in the *British Pharmacopoeia* or the *British Pharmacopoeia (Veterinary)*; and
- (c) the goods are not labelled or packaged in accordance with those requirements;

the goods are to be taken not to comply with that standard.

(4) Where:

- (a) a standard under section 10 applies to therapeutic goods; and
- (b) requirements applicable to the goods are specified in the *British Pharmacopoeia* or the *British Pharmacopoeia (Veterinary)*; and
- (c) those requirements are inconsistent with the requirements specified in the standard;

the requirements referred to in paragraph (b) are, so far as they are inconsistent, to be disregarded for the purposes of this Act.

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(5) Where:

- (a) a standard applies to a class of therapeutic goods; and
- (b) another standard applies to some only of the therapeutic goods within that class; and
- (c) those standards are inconsistent;

the standard referred to in paragraph (a) is, to the extent of the inconsistency, of no effect in relation to the goods referred to in paragraph (b).

(6) Where:

- (a) therapeutic goods consist, or are represented to consist, of a mixture of ingredients or of a combination of component parts; and
- (b) a standard is applicable to the mixture or the combination;

that standard takes precedence over any standard that is applicable to the ingredients or the component parts.

(7) Where:

- (a) therapeutic goods consist, or are represented to consist, of a mixture of ingredients or of a combination of component parts; and
- (b) there is no standard applicable to the goods but a standard is applicable to at least one of the ingredients or component parts; and
- (c) the Minister has, by order published in the *Gazette*, determined that the standard does not apply to the goods;

the standard is to be disregarded in so far as it would otherwise apply to the goods.

Compliance with standards

14. (1) Except with the consent in writing of the Secretary, a person must not:

- (a) import therapeutic goods into Australia; or
- (b) supply therapeutic goods for use in Australia;

if the goods do not conform with a standard applicable to the goods.

Penalty: \$24,000.

(2) Paragraph (1) (a) does not apply to goods that do not conform with a standard applicable to the goods by reason only of matters relating to labelling or packaging.

(3) Except in exceptional circumstances and with the consent in writing of the Secretary, a person must not export therapeutic goods from Australia if the goods do not conform with a standard applicable to the goods (other than a standard relating to the labelling of the goods for supply in Australia).

Penalty: \$24,000.

(4) Where:

- (a) the importation or exportation of goods is prohibited under subsection (1) or (3); and

- (b) the Secretary notifies the Comptroller-General in writing that the Secretary wishes the *Customs Act 1901* to apply to that importation or exportation,

the goods are, for the purposes of that Act, to be taken to be prohibited imports or prohibited exports, as the case may be.

(5) 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 *Gazette*.

(6) 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.

Consent may be subject to conditions etc.

15. (1) The consent of the Secretary under section 14 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

Forms etc. of therapeutic goods

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

- (a) a different formulation, composition or design specification; or
- (b) a different strength or size (disregarding pack size); or
- (c) a different dosage form or model; or
- (d) a different name; or
- (e) different indications; or
- (f) different directions for use; or
- (g) a different type of container (disregarding container size).

(2) The Secretary may, by order published in the *Gazette*, determine that a group of therapeutic goods identified in the order is, because of the common characteristics of the goods within the group, to be treated as single therapeutic goods for the purposes of this Part.

Australian Register of Therapeutic Goods

17. (1) The Secretary is to cause to be maintained a register, to be known as the Australian Register of Therapeutic Goods, for the purpose of compiling information in relation to, and providing for evaluation of, therapeutic goods for use in humans.

(2) Subject to subsection (3), the Register is to be kept in such form as the Secretary determines.

(3) The Register is to contain 2 parts, one relating to goods to be known as registered goods and the other relating to goods to be known as listed goods.

(4) The regulations may:

- (a) prescribe the therapeutic goods, or the classes of therapeutic goods, that are required to be included in each part of the Register; and
- (b) prescribe the ways in which goods that are included in one part of the Register may be transferred, or may be required to be transferred, to the other part of the Register.

Exempt goods

18. (1) The regulations may, subject to such conditions (if any) as are specified in the regulations, exempt therapeutic goods or a class of therapeutic goods identified in the regulations from the operation of this Part.

(2) Where the regulations revoke an exemption, the revocation takes effect on the day, not being earlier than 28 days after the day on which the regulations are made, as is specified in the regulations.

Exemptions for special and experimental uses

19. (1) The Secretary may, by notice in writing, grant an approval to a person for the importation into, or the exportation from, Australia or the supply in Australia of 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;

and such an approval may be given subject to such conditions as are specified in the notice of approval.

(2) An application for an approval must be made to the Secretary and must:

- (a) in the case of an application for use of the kind referred to in paragraph (1) (a)—be accompanied by such information relating to the goods the subject of the application as is required by the Secretary; and
- (b) in the case of an application for use of the kind referred to in paragraph (1) (b):
 - (i) be made in writing; and
 - (ii) be accompanied by such information relating to the goods the subject of the application as is required by the Secretary; and
 - (iii) be accompanied by the prescribed evaluation fee.

(3) Without limiting the conditions to which an approval under subsection (1) may be made subject, those conditions may include a condition relating

to the charges that may be made for the therapeutic goods to which the approval relates.

(4) Where an application for an approval is made, the Secretary must, after having considered the application and, in the case of an application for the use of therapeutic goods for experimental purposes in humans, after having evaluated the information submitted with the application, notify the applicant of the 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.

Offences by sponsors

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

- (a) import the goods into Australia for use in humans; or
- (b) export the goods from Australia for use in humans; or
- (c) manufacture the goods for supply in Australia for use in humans;
or
- (d) supply the goods in Australia for use in humans;

unless:

- (e) the goods are registered goods or listed goods in relation to the person; or
- (f) the goods are exempt goods or are the subject of an approval under section 19.

Penalty: \$24,000.

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

- (a) import those goods into Australia; or
- (b) export those goods from Australia; or
- (c) supply those goods in Australia;

unless:

- (d) the registration number or listing number of the goods is set out on the label of the goods in the prescribed manner or, in the case of an importation, that number is so set out, or is to be so set out before the goods are supplied in Australia; or
- (e) the goods are devices that are listed goods or are listed goods that have been manufactured in Australia for export only.

Penalty: \$6,000.

(3) Where:

- (a) the importation or exportation of goods is prohibited under subsection (1); and
- (b) the Secretary notifies the Comptroller-General in writing that the Secretary wishes the *Customs Act 1901* to apply to that importation or exportation;

the goods are, for the purposes of that Act, to be taken to be prohibited imports or prohibited exports, as the case may be.

Offence relating to wholesale supply

21. A person must not knowingly or recklessly supply in Australia therapeutic goods for use in humans (other than listable devices), being goods of which the person is not a sponsor, to another person who is not the ultimate consumer of the goods unless:

- (a) the goods are registered goods or listed goods; or
- (b) the goods are exempt goods or are the subject of an approval under section 19.

Penalty: \$12,000.

General offences relating to this Part

22. (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 registration or listing of therapeutic goods, make a statement that is, to the person's knowledge, 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 subsection 18 (1); or

(b) an approval under section 19.

(8) 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 under section 19.

Penalty: \$6,000.

Division 2—Registration and Listing

Applications generally

23. An application for registration or listing of therapeutic goods must:

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

(b) be delivered to an office of the Department specified by the Secretary; and

(c) be accompanied by the prescribed application fee and by such information, in the form approved by the Secretary, as will allow the determination of the application; and

(d) if the Secretary so requires—be accompanied by a reasonable number of samples of the goods.

Applications for registration

24. (1) Where an application is made for the registration of therapeutic goods in accordance with section 23 and the goods are goods that are required to be registered, a fee specified in or determined in accordance with the regulations is payable 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) An application for registration of therapeutic goods lapses if, at the end of the period of 2 months after the day on which the applicant was notified of the amount of the evaluation fee, the evaluation fee in respect of those goods has not been paid.

Evaluation of therapeutic goods

25. (1) Where:

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

(b) the evaluation fee in respect of the goods has been paid; and

(c) the person has complied with any requirements made by the Secretary under section 31 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

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- (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 under the regulations; and
 - (g) if a step in the manufacture of the goods has been carried out outside Australia—whether the manufacturing and quality control procedures used in the manufacture of the goods are acceptable; and
 - (h) if the goods have been manufactured in Australia—whether the goods have been manufactured in accordance with Part 4; and
 - (j) whether the goods contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; and
 - (k) such other matters (if any) as the Secretary considers relevant.
- (2) In making a decision for the purposes of paragraph (1) (g), the matters that may be taken into account include:
- (a) whether the applicant has provided an acceptable form of evidence from a relevant overseas authority to establish that the manufacture of the goods is of an acceptable standard; and
 - (b) whether the applicant has agreed to provide, where the Secretary considers inspection of the manufacturing procedures used in the manufacture of the goods to be necessary:
 - (i) funds for the carrying out of that inspection by the Department; and
 - (ii) evidence that the manufacturer has agreed to such an inspection.
- (3) 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—give to the applicant a Register form to be filled in by the applicant in relation to the goods.
- (4) As soon as practicable after receiving the completed signed Register form, the Secretary must give to the applicant a certificate of registration of the goods.
- (5) The registration of therapeutic goods commences on the day specified for the purpose in the certificate of registration.

Listing of therapeutic goods

26. (1) Where:

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

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- (b) the person has complied with any requirements made by the Secretary under section 31 in relation to the goods;

the Secretary is not to refuse to list the goods in relation to the person except where 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 under the regulations; or
- (g) if a step in the manufacture of the goods (not being therapeutic devices other than devices prescribed for the purposes of this paragraph) has been carried out outside Australia—the manufacturing and quality control procedures used in the manufacture of the goods are not acceptable; or
- (h) if the goods have been manufactured in Australia—the goods have been manufactured contrary to Part 4; or
- (j) if the goods have been manufactured in Australia solely for export and:
 - (i) the goods have been refused registration or listing for supply in Australia; or
 - (ii) the Secretary requires such a confirmation for other reasons; a relevant authority of the country to which the goods are to be exported has not confirmed its willingness to accept the goods; or
- (k) the goods do not comply with prescribed quality or safety criteria; or
- (m) the goods contain substances that are prohibited imports for the purposes of the *Customs Act 1901*.

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

- (a) whether the applicant has provided an acceptable form of evidence from a relevant overseas authority to establish that the manufacture of the goods is of an acceptable standard; and
- (b) whether the applicant has agreed to provide, where the Secretary considers inspection of the manufacturing procedures used in the manufacture of the goods to be necessary:
 - (i) funds for the carrying out of that inspection by the Department; and
 - (ii) evidence that the manufacturer has agreed to such an inspection.

(3) 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 include the goods in the list, of the reasons for the decision.

(4) As soon as practicable after an applicant has been informed that the therapeutic goods in respect of which the 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.

Registration or listing number

27. Where the Secretary includes therapeutic goods in the Register, the Secretary is to assign a unique registration or listing number to the goods.

Conditions on registration or listing

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

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

- (a) the manufacture of the goods; 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 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.

(5) 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.

Duration of registration or listing

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

Cancellation of registration or listing

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

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

(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 goods become required to be included in the other part of the Register; or
- (e) the goods do not conform to a standard applicable to the goods or to a requirement relating to advertising applicable to the goods under the regulations; or
- (f) 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

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- (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 paragraph (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 *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 paragraph (6) (a) is guilty of an offence.

Penalty for a contravention of this subsection: \$6,000.

Division 3—General

Secretary may require information

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

- (a) the formulation of the goods;
- (b) the composition of the goods;
- (c) the design specifications of the goods;
- (d) the quality of the goods;
- (e) the method and place of manufacture or preparation of the goods and the procedures employed to ensure that proper standards are maintained in the manufacture and handling of the goods;
- (f) the presentation of the goods;

- (g) the safety and efficacy of the goods for the purposes for which they are to be used;
- (h) the conformity of the goods to a requirement relating to advertising applicable under the regulations;
- (j) the regulatory history of the goods in another country;
- (k) any other matter prescribed by the regulations for the purposes of this paragraph 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 manufacturer 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 the goods under the regulations;
- (h) any other matter prescribed by the regulations for the purposes of this paragraph in relation to goods of that kind.

Inspection and variation of entries in Register

32. (1) The Register is not open for public inspection, but 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 the person (other than any part of that entry that was supplied in confidence by another person).

(2) Such fee (if any) as is prescribed is payable in respect of the processing of such a request.

(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.

Publication of list of goods on Register

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

PART 4—MANUFACTURING OF THERAPEUTIC GOODS

Exempt goods and exempt persons

34. (1) The regulations may exempt therapeutic goods or a class of therapeutic goods identified in the regulations from the operation of this Part.

(2) The regulations may exempt a person identified in the regulations from the operation of this Part in relation to the manufacture or a step in the manufacture of therapeutic goods or a class of therapeutic goods identified in the regulations.

(3) Where the regulations revoke an exemption, the revocation takes effect on the day, not being earlier than 28 days after the day on which the regulations are made, as is specified in the regulations.

Offences relating to manufacturing and licences

35. (1) A person must not, at premises in 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 that is in force 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 for a contravention of this subsection: \$6,000.

Manufacturing principles

36. (1) The Minister may, from time to time, determine written principles to be observed in the manufacture of therapeutic goods for use in humans.

(2) The manufacturing principles may relate to:

- (a)** the standards to be maintained, and the equipment to be used, at premises used for the manufacturing of therapeutic goods for use in humans; or
- (b)** procedures for quality assurance and quality control to be employed in the manufacturing of therapeutic goods for use in humans; or
- (c)** the qualifications and experience required of persons employed in the manufacture of therapeutic goods for use in humans; or

- (d) the manufacturing practices to be employed in the manufacturing of therapeutic goods for use in humans; or
- (e) other matters relevant to the quality, safety and efficacy of therapeutic goods for use in humans that are manufactured in Australia;

and may include codes of good manufacturing practice.

(3) The Minister may, before taking action under subsection (1) in relation to the manufacturing principles, obtain advice from a committee established by the regulations on the action that should be taken under that subsection as to the principles to be observed in the manufacture of therapeutic goods for use in humans.

(4) Manufacturing principles are disallowable instruments for the purposes of section 46A of the *Acts Interpretation Act 1901*.

Application for licence

37. (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 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 Department specified in the form; and
- (g) be accompanied by the prescribed application fee.

(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.

Grant of licence

38. (1) Where:

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

- (b) the prescribed application fee has been paid; and
- (c) any applicable prescribed inspection fees have been paid; and
- (d) the person has complied with any requirements made by the Secretary under subsection 37 (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 revoked; or
 - (ii) has been convicted of an offence against this Act or a law of a 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) Notwithstanding paragraph (1) (f), the Secretary may grant a licence to a person who, apart from this subsection, could not be granted a licence because of that paragraph 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 *Gazette* as soon as is practicable after the decision is made.

Term of licence

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

Conditions of licences

40. (1) A licence may be granted subject to:
- (a) conditions designed to ensure that the holder of the licence manufactures the goods in accordance with the manufacturing principles and any standards applicable to the goods; and
 - (b) such other conditions relating to the manufacture of the goods as the Secretary thinks appropriate.

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(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 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 subparagraph (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 regulations for the purposes of this section.

Revocation and suspension of licences

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

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

- (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 prescribed 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 prescribed 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 paragraph (2) (b), the Secretary is not to make a decision relating to the revocation or suspension of the licence before taking into account the submissions.

(4) A licence may be revoked 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 *Gazette* as soon as is practicable after the decision is made.

Publication of list of manufacturers etc.

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

PART 5—PAYMENT OF CHARGES

By whom charges payable

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

(2) An annual licensing charge is payable by the holder of the licence to which the charge relates.

Time for payment of charges

44. (1) An annual registration charge or annual listing charge for a financial year becomes payable:

(a) if the charge is imposed in respect of therapeutic goods the registration or listing of which commenced before 1 July 1990:

(i) in the case of charge for the financial year commencing on 1 July 1990—on that day; or

(ii) in the case of a later financial year—on 1 July in that financial year or, if the Secretary has, by notice in writing given before 1 July 1991 to the person in relation to whom the therapeutic goods concerned are registered or listed, specified another day as being the day on which the charge becomes payable, on the specified day or on an anniversary of that day, as the case requires; or

(b) in any other case:

(i) if the year is the financial year (in this paragraph called the “first year”) during which the registration or listing of the therapeutic goods concerned commenced—on that commencement; or

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

(2) An annual licensing charge for a financial year becomes payable:

(a) if the licence commenced before 1 July 1990—on 1 July 1990 and on each anniversary of that day; or

(b) in any other case—on the day on which the licence commenced and on each anniversary of that day.

(3) The Secretary may, by agreement with the person by whom an annual registration charge, an annual listing charge or an annual licensing charge is payable, vary the day on which the charge becomes payable in a financial year.

Money to be paid into trust account

45. (1) Amounts equal to amounts received by the Commonwealth by way of annual registration charge, annual listing charge and annual licensing charge are to be paid into the trust account established under the *Audit Act 1901* and known as the Therapeutic Goods Administration Trust Account.

(2) Payments under subsection (1) are to be made out of the Consolidated Revenue Fund, which is appropriated accordingly.

PART 6—MISCELLANEOUS

Monitoring compliance with Act

46. (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 subsection 48 (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 49 authorises the entry or the exercise of the power.

Entry and search of premises—evidence of offences

47. (1) Subject to subsection (3), an authorised person who 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 subsection 48 (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 60 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 50 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 50, 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) the authorised person 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.

General powers of authorised persons in relation to premises

48. (1) The powers an authorised person may exercise under paragraph 46 (1) (b) or 47 (1) (b) in relation to premises are as follows:

- (a) to search any part of the premises;
- (b) to inspect, examine, take measurements 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 49 or 50—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 subsections 46 (2) and 47 (3).

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

Monitoring warrants

49. (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 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 subsection 48 (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.

Offence related warrants

50. (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 being 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 subsection 48 (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.

Offence related warrants by telephone

51. (1) If, in an urgent case, an authorised person considers it necessary to do so, the person may apply to a magistrate by telephone for a warrant under section 50 in relation to premises.

(2) Before applying for the warrant, the person must prepare an information of the kind mentioned in subsection 50 (2) in relation to the premises that sets out the grounds on which the warrant is sought.

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

- (4) If the magistrate is satisfied:**
- (a) after having considered the terms of the information; and
 - (b) after having received such further information (if any) as the magistrate requires concerning the grounds on which the issue of the warrant is being sought;

that there are reasonable grounds for issuing the warrant, the magistrate may complete and sign the same warrant that the magistrate would issue under section 50 if the application had been made under that section.

- (5) If the magistrate completes and signs the warrant:**
- (a) the magistrate must:
 - (i) tell the authorised person what the terms of the warrant are; and
 - (ii) tell the person the day on which and the time at which the warrant was signed; and
 - (iii) tell the authorised person the day (not more than one week after the magistrate completes and signs the warrant) on which the warrant ceases to have effect; and

- (iv) record on the warrant the reasons for granting the warrant; and
- (b) the person must:
 - (i) complete a form of warrant in the same terms as the warrant completed and signed by the magistrate; and
 - (ii) write on the form the name of the magistrate and the day on which and the time at which the warrant was signed.
- (6) The person must also, not later than the day after the day of expiry or execution of the warrant, whichever is the earlier, send to the magistrate:
 - (a) the form of warrant completed by the person; and
 - (b) the information referred to in subsection (2), which must have been duly sworn.
- (7) When the magistrate receives those documents, the magistrate must:
 - (a) attach them to the warrant that the magistrate completed and signed; and
 - (b) deal with them in the way in which the magistrate would have dealt with the information if the application had been made under section 50.
- (8) A form of warrant duly completed under subsection (5) is authority for any entry, search, seizure or other exercise of a power that the warrant signed by the magistrate authorises.
- (9) If:
 - (a) it is material, in any proceedings, for a court to be satisfied that an exercise of a power was authorised by this section; and
 - (b) the warrant signed by the magistrate authorising the exercise of the power is not produced in evidence;the court must assume, unless the contrary is proved, that the exercise of the power was not authorised by such a warrant.
- (10) A reference in this Part to a warrant under section 50 includes a reference to a warrant signed by a magistrate under this section.

Identity cards

52. (1) The Secretary is to ensure that each authorised person is issued with an identity card that incorporates a recent photograph of the person.

(2) Where an authorised person 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, the person must, as soon as practicable after so ceasing, return the person's identity card to the Secretary.

Penalty for an offence against this subsection: \$100.

Retention of material on withdrawal of applications

53. Where a person withdraws an application for registration or listing of therapeutic goods or an application for a licence, the Department may retain the application and any material submitted in connection with the application.

Offences

54. (1) An offence against section 14, 15 or 21 or subsection 20 (1) or 35 (1) or (2) is an indictable offence.

(2) In proceedings for an offence against section 14, a certificate by the Secretary to the effect that:

- (a) the Secretary did not consent to the importation, supply or export the subject of the proceedings; or
- (b) the Secretary consented to that importation, supply or export subject to conditions specified in the certificate;

is *prima facie* evidence of the matters specified in the certificate.

(3) Where a court convicts a person of an offence against this Act in relation to any therapeutic goods (other than an indictable offence), the court may order that the goods be forfeited to the Commonwealth and, where such an order is made, the goods become the property of the Commonwealth.

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

(5) Goods forfeited under an order referred to in subsection (3) are to be disposed of in such manner as the Secretary directs.

Conduct by directors, servants and agents

55. (1) Where, in proceedings for an offence against this Act, it is necessary to establish the state of mind of a body corporate in relation to particular conduct, it is sufficient to show:

- (a) that the conduct was engaged in by a director, servant or agent of the body corporate within the scope of his or her actual or apparent authority; and
- (b) that the director, servant or agent had the state of mind.

(2) Any conduct engaged in 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.

(9) A reference in this section to an offence against this Act includes a reference to:

(a) an offence against the regulations; and

(b) an offence created by section 6, 7 or 7A, or subsection 86 (1), of the *Crimes Act 1914*, being an offence that relates to this Act or the regulations.

Judicial notice

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

Delegation

57. (1) Subject to subsection (2), the Minister or the Secretary may, by signed instrument, delegate to:

(a) an officer of the Department; or

(b) an officer of another Department or of an authority of the Commonwealth that has functions in relation to therapeutic goods;

all or any of his or her powers and functions under this Act.

(2) The powers of the Secretary under paragraph 19 (1) (a) may be delegated only to an officer of the Department who is registered, or eligible for registration, in a State or internal Territory, as a medical or dental practitioner.

Export certifications

58. (1) The Secretary may issue export certifications for goods for therapeutic use in humans, including certifications for the purposes of the World Health Organisation Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

(2) A State or Territory must not issue export certifications for goods for therapeutic use in humans.

(3) Such fee as is prescribed is payable in respect of:

(a) the issue of a certification under this section; and

(b) where an inspection of manufacturing premises is necessary for the purposes of the issue of a certification under this section—the inspection of those premises.

Fees

59. (1) No fees are payable under this Act in respect of an event occurring before 1 July 1990.

(2) Fees prescribed under this Act must not be such as to amount to taxation.

(3) No licence or inspection fees are to apply to non-profit hospital supply units.

Review of decisions

60. (1) In this section:

“**decision**” has the same meaning as in the *Administrative Appeals Tribunal Act 1975*;

“**initial decision**” means a decision of the Secretary or of a delegate of the Secretary:

(a) under the definition of “therapeutic devices” in subsection 3 (1) or under subsection 7 (1); or

(b) refusing to grant a consent under section 14; or

(c) under Part 3 or 4;

“**reviewable decision**” means a decision of the Minister under subsection (3).

(2) A person whose interests are affected by an initial decision may, by notice in writing given to the Minister:

(a) in the case of a decision particulars of which are required to be notified in the *Gazette*—within 90 days after those particulars are so notified; or

(b) in any other case—within 90 days after the decision first comes to the person's notice;
request the Minister to reconsider the decision.

(3) The Minister must, as soon as practicable after receiving a request under subsection (2), reconsider the initial decision and, as a result of that reconsideration, may:

- (a) confirm the initial decision; or
- (b) revoke the initial decision, or revoke that decision and make a decision in substitution for the initial decision.

(4) Where a person who has made a request under subsection (2) does not receive notice of the decision of the Minister on reconsideration within 60 days of the making of the request, the Minister is to be taken to have confirmed the original decision.

(5) After reconsideration of an initial decision, the Minister must give the applicant a notice in writing stating the result of the reconsideration and that the applicant may, except where subsection 28 (4) of the *Administrative Appeals Tribunal Act 1975* applies, apply for a statement setting out the reasons for the decision on reconsideration and may, subject to that Act, make an application to the Administrative Appeals Tribunal for review of that decision.

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

- (a) seek a reconsideration of the decision under this section; and
- (b) subject to the *Administrative Appeals Tribunal Act 1975*, if the person is dissatisfied with the decision upon reconsideration, make an application to the Administrative Appeals Tribunal for review of that decision.

(7) Any failure to comply with the requirements of subsection (5) or (6) in relation to a decision does not affect the validity of the decision.

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

Release of information

61. (1) In this section:

“therapeutic goods information” means information in relation to therapeutic goods that came into the possession of the Department in connection with the performance of the Department's functions.

(2) The Secretary may:

- (a) release to the Director-General of the World Health Organisation therapeutic goods information relating to:
 - (i) notifications concerning therapeutic goods the consumption

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or supply of which in Australia has been prohibited or severely restricted, or relating to the reasons for that action;
or

- (ii) the licensing status of Australian manufacturers of therapeutic goods and their compliance with the manufacturing principles;
or
- (iii) the content of reports to the Department concerning adverse effects of therapeutic goods;

for use in the development of policies relating to the regulation of therapeutic goods or for the provision of information to regulatory authorities of member countries of the World Health Organisation;
or

- (b) release, in confidence, therapeutic goods information to the Director-General of the World Health Organisation, being information concerning proceedings of committees established under the regulations.

(3) The Secretary may release to the head of an authority of the Commonwealth, a State or a Territory that has functions relating to therapeutic goods, therapeutic goods information relating to:

- (a) reported problems and complaints concerning therapeutic goods, the Department's investigation of those problems and complaints and any action that the Department has taken or proposes to take in relation to those problems and complaints; or
- (b) reports of inspections conducted under this Act or the regulations;
or
- (c) decisions to revoke or suspend, or not to issue, licences for the manufacturing of therapeutic goods; or
- (d) conditions of licences; or
- (e) reports of the testing of samples of therapeutic goods;

for use in the performance of those functions.

(4) The Secretary may release to the head of a national regulatory authority of another country, being an authority that has national responsibility relating to therapeutic goods, therapeutic goods information relating to:

- (a) recommendations of advisory committees on therapeutic goods supplied in or proposed for supply in Australia, and any conditions that are or will be applicable to that supply; or
- (b) decisions on the registration or listing, or the cancellation of the registration or listing, of therapeutic goods; or
- (c) the withdrawal from supply in Australia of therapeutic goods and the reasons for that action; or
- (d) the licensing status of Australian manufacturers of therapeutic goods and their compliance with the manufacturing principles; or
- (e) proceedings of committees established under the regulations;

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for use in the performance of those functions or for furthering international co-operation in the regulation of therapeutic goods.

(5) The Secretary may release to the head of a national regulatory authority of another country, or the head of an international organisation, being another country or an organisation with which the Commonwealth has co-operative arrangements relating to the assessment or regulation of therapeutic goods, therapeutic goods information the release of which is consistent with those arrangements.

(6) The Secretary may release to a person, on application by that person, therapeutic goods information of a kind identified in the regulations relating to therapeutic goods included in the Register.

(7) The Secretary may release therapeutic goods information:

- (a) the release of which is necessary to ensure the safe use of particular therapeutic goods; or
- (b) relating to the reasons for the withdrawal of therapeutic goods from supply in Australia.

(8) Therapeutic goods information provided to the Department in relation to a matter may:

- (a) be used by the Department in the consideration of another matter within its functions relating to therapeutic goods; and
- (b) be provided to a committee appointed to advise the Minister or the Secretary on matters relating to therapeutic goods, including a committee of the National Health and Medical Research Council.

(9) Civil proceedings do not lie against the Secretary or a delegate of the Secretary in respect of loss, damage or injury of any kind suffered by another person as a result of the release of information in good faith under this section or the regulations.

(10) This section has effect subject to the *Freedom of Information Act 1982*.

Consequential amendments

62. The Acts specified in the Schedule are amended as set out in the Schedule.

Regulations

63. (1) The Governor-General may make regulations, not inconsistent with this Act, prescribing matters:

- (a) required or permitted to be prescribed by this Act; or
- (b) necessary or convenient to be prescribed for carrying out or giving effect to this Act.

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- (2) The regulations may:**
- (a) make provision in relation to:**
 - (i) the establishment of committees to advise the Minister or the Secretary on matters relating to therapeutic goods; and**
 - (ii) the functions and powers of those committees; and**
 - (iii) the payment of remuneration and allowances to members of those committees; and**
 - (b) prescribe requirements for the storage and transport of therapeutic goods; and**
 - (c) prescribe requirements for the advertising of therapeutic goods; and**
 - (d) provide for the procedures to be followed by the Department in the sampling and testing of therapeutic goods; and**
 - (e) prescribe requirements for informational material that is included with therapeutic goods; and**
 - (f) make provision for the transfer of registration or listing of therapeutic goods and of licences; and**
 - (g) make provision for the testing of therapeutic goods, the inspection of manufacturing operations or the evaluation of data concerning therapeutic goods by the Department at the request of persons, and prescribe fees for those services; and**
 - (h) prescribe fees for the inspection of manufacturing premises and procedures; and**
 - (j) prescribe penalties not exceeding \$1,000 for offences against the regulations.**
- (3) The regulations may:**
- (a) prescribe different fees under this Act in relation to:**
 - (i) different classes of goods; or**
 - (ii) in the case of fees under Part 4—different steps in the manufacture of goods; or**
 - (b) provide for the refund, reduction or waiving of fees or charges in cases identified in the regulations; or**
 - (c) specify the type of information relating to therapeutic goods manufactured by licence holders that the Secretary may, under subsection 37 (2), require to be supplied by the holders of licences at the time of payment of annual licensing charges in respect of the licences.**
- (4) The regulations may make provision for a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument:**
- (a) as that instrument is in force at the time when the regulations take effect; or**
 - (b) as that instrument is in force from time to time.**

(5) For the purposes of section 2, regulations may be made before the commencement of this Act as if this Act were in force, but do not come into effect on a day earlier than the day on which this Act commences.

PART 7—REPEAL AND TRANSITIONAL PROVISIONS

Interpretation

64. In this Part, “former Act” means the *Therapeutic Goods Act 1966*.

Repeal

65. The former Act is repealed.

Transitional arrangements for goods required to be registered or listed

66. (1) This section applies to therapeutic goods in relation to a person if, immediately before the commencement of this Act, the person was supplying goods of that kind in Australia for use in humans.

(2) Where:

- (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 Act; 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*;

subsections 20 (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) Where:

- (a) this section applies to therapeutic goods in relation to a person; and
- (b) the person makes an application for registration or listing of goods of that kind in accordance with section 23 and within 3 months after the commencement of this Act;

then:

- (c) subsection 20 (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 *Gazette* before the end of that first-mentioned period; and
- (d) subsection 20 (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 *Gazette* before the end of that first-mentioned period.

(4) 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—any fee for the evaluation of the goods for registration;

but where the goods are later evaluated to determine whether the goods should continue to be registered, such fee as is prescribed is payable in respect of that evaluation.

(5) Section 21 does not apply, during the period of 15 months after the commencement of this Act or during such longer period as the Secretary specifies by notice published in the *Gazette* before the end of that first-mentioned period, to any goods.

Transitional provision for therapeutic goods for export only

67. Section 20 does not apply, during the period of 6 months after the commencement of this Act, to therapeutic goods manufactured in Australia solely for export from Australia.

Transitional arrangements for Part 4

68. (1) This section applies to a step in the manufacture of therapeutic goods in relation to a person in relation to premises in Australia if, before the commencement of this Act, 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 Act;

subsection 35 (1) does not apply 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 37 and within 4 months after the commencement of this Act;

subsection 35 (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.

Continuation of standards and requirements

69. Any standards that were in force immediately before the commencement of this Act under Part 2 of the former Act, and any requirements that were in force at that time under section 15 of the former Act, continue in force as if they were standards made under Part 2 of this Act.

SCHEDULE

Section 62

CONSEQUENTIAL AMENDMENTS

Agricultural and Veterinary Chemicals Act 1988

Section 5:

Omit "*Therapeutic Goods Act 1966*", substitute "*Therapeutic Goods Act 1989*".

Commonwealth Serum Laboratories Act 1961

Subsection 4 (1) (definition of "therapeutic use"):

Omit "*Therapeutic Goods Act 1966*", substitute "*Therapeutic Goods Act 1989*".

Subsection 6 (2):

Omit "*Therapeutic Goods Act 1966*", substitute "*Therapeutic Goods Act 1989*".

Sea Installations Act 1989

Schedule:

Omit "*Therapeutic Goods Act 1966*", substitute "*Therapeutic Goods Act 1989*".

[*Minister's second reading speech made in—
House of Representatives on 26 October 1989
Senate on 12 December 1989*]