NORTHERN TERRITORY OF AUSTRALIA

THERAPEUTIC GOODS AND COSMETICS ACT 1986

No. 46 of 1986

TABLE OF PROVISIONS

Section

G. L. DUFFIELD, Government Printer of the Northern Territory

PART IV - SAMPLES AND ANALYSIS, &c.

PART V - DEALINGS WITH SEIZED GOODS, &c.

PART VI - ADVERTISING, &c.

PART VII - OFFENCES

PART VIII - APPEALS

PART IX - MISCELLANEOUS

PART X - REGULATIONS, &c.

PART XI - TRANSITIONAL

NORTHERN TERRITORY OF AUSTRALIA

No. 46 of 1986

AN ACT

to regulate the manufacture, distribution, labelling and advertising of therapeutic goods and certain articles of food, to make provision in relation to standards for therapeutic goods and cosmetics and goods for veterinary use only, and for related purposes

[Assented to 21 October 1986]

BE it enacted by the Legislative Assembly of the Northern Territory of Australia, with the assent as provided by the *Northern Territory (Self-Government) Act* 1978 of the Commonwealth, as follows:

PART I - PRELIMINARY

1. SHORT TITLE

This Act may be cited as the *Therapeutic Goods and Cosmetics Act 1986*.

2. COMMENCEMENT

This Act shall come into operation on a date to be fixed by the Administrator by notice in the *Gazette*.

3. ACT TO BIND THE CROWN

This Act binds the Crown.

4. INTERPRETATION

(1) In this Act, unless the contrary intention appears -

"advertisement", in relation to therapeutic goods or cosmetics, means an advertisement that is published for the purpose of promoting, whether directly or indirectly, the sale or use of those therapeutic goods or cosmetics;

"analysis", in relation to therapeutic goods or cosmetics, means a bacteriological, biochemical, biological, chemical, electrical, electrochemical, microscopical, pathological, physical or other examination or test for ascertaining the presence or absence of a substance or organism or the composition or other qualities of those therapeutic goods or cosmetics;

"analyst" means a person appointed under section 12(1) to be an analyst;

"appliance" includes -

(a) an instrument, apparatus, contrivance or device; and

(b) a component, part or accessory of an instrument, apparatus, contrivance or device,

that is sold, or is represented as suitable, for therapeutic use or cosmetic use;

"approved" means approved by the Minister;

"article of food" means a substance of a kind ordinarily consumed or intended to be consumed by man as food, and includes -

(a) drink;

(b) chewing gum;

(c) an ingredient, food additive or other substance that is ordinarily used for or in connection with the composition or preparation of food; and

(d) a substance declared under section 6(a)(v) to be food for the purposes of this Act;

"certificate of analysis", in relation to therapeutic goods or cosmetics, means a certificate prepared under section 15(1) setting out the result of an analysis by an analyst of those goods or cosmetics;

"certificate of appointment", in relation to an inspector, means the certificate furnished under section 9(5) to him by the Minister in respect of his appointment as an inspector;

"certificate of examination", in relation to therapeutic goods or cosmetics, means a certificate prepared under section 15(2) setting out the result of an examination under section 10(2)(d) or (e) of those goods or cosmetics;

"Commonwealth Act" means the *Therapeutic Goods Act 1966* of the Commonwealth;

"contained", in relation to therapeutic goods or cosmetics, includes enclosed and kept;

"container", in relation to therapeutic goods or cosmetics, means a vessel, bottle, tube, tin, box, case, wrapper, cover, envelope or other receptacle that immediately contains those goods or cosmetics;

"cosmetics" means goods that are, or are included in, a class of goods -

(a) the use or principal use of which is, or ordinarily is, a cosmetic use;

(b) represented to be, or that might reasonably be taken to be, for cosmetic use; or

(c) used, or designed for use, or intended to be used as a component of goods to which paragraph (a) or (b) relates,

and includes a substance the subject of a notice under section 6(a)(iii), but does not include -

(d) therapeutic goods; or

(e) a substance the subject of a notice under section 6(a)(iv);

"court" means court of summary jurisdiction;

"dentist" means a registered dentist within the meaning of the *Dentists Registration Act*;

"expiry date", in relation to therapeutic goods or cosmetics, means a day after which those goods or cosmetics may be expected to cease to conform to a standard applicable to them;

"goods for veterinary use only" means goods that -

(a) bear particulars on their container that constitute, or might reasonably be taken for, a statement that the goods are intended for veterinary use and are not intended for human use; or

(b) are otherwise represented, whether by writing or otherwise, or otherwise purport, to be intended for veterinary use and not for human use;

"hawk", in relation to therapeutic goods, means -

(a) sell or supply those goods, or distribute those goods free or as samples, in a public street or from place to place;

(b) peddle those goods; or

(c) go from place to place, whether by appointment or otherwise, selling, supplying or distributing those goods, whether free or as samples;

"inspector" means a person appointed under section 9(1) to be an inspector for the purposes of this Act, and includes an officer under an arrangement referred to in section 9(2) and a member of the Police Force within the meaning of the *Police Administration Act*;

"label" includes a tag, brand, mark and statement in writing on or attached to, or used in connection with, a container or package containing therapeutic goods or cosmetics;

"licence" means a licence granted under section 17(1)(a), and includes a renewal of such a licence;

"nurse" means a registered nurse within the meaning of the *Nursing Act*;

"package", in relation to therapeutic goods or cosmetics, includes a means by which those goods or cosmetics may, for transport, carriage or sale, be wholly or partly cased, covered, enclosed, contained or packaged;

"permit" means a permit granted under section 18(3)(a), and includes a renewal of such a permit;

"pharmacist" means a registered pharmacist within the meaning of the *Pharmacy Act*;

"public institution" means -

(a) a hospital within the meaning of the *Hospitals and Medical Services Act*; or

(b) a nursing institution declared under section 7 to be a public institution;

"publish" means to bring to the notice of the public or a section of the public by any means;

"seized goods" means goods seized under section 10(2)(g);

"sell" means sell, whether by wholesale or retail, and includes -

(a) offer or expose for sale;

(b) keep or have in possession for sale; and

(c) sell for or in expectation of a reward or benefit paid or provided, or to be paid or provided, by the person supplied or another person, whether or not any person was or is under an obligation to pay or provide a reward or benefit;

"standard", in relation to therapeutic goods or cosmetics, means a prescribed standard applicable to or in relation to those goods or cosmetics;

"substance" includes a preparation, admixture, salt or derivative of a substance;

"supply" includes offer or agree to supply;

"Territory authority" means a person or body of persons constituted, established or appointed under an Act, or in the exercise of the prerogative rights of the Crown, to administer or control a department, business, undertaking or institution on behalf of the Territory;

"therapeutic appliance" means an appliance that is -

(a) included in a class of appliances the sole or principal use of which is, or ordinarily is, a therapeutic use;

(b) represented to be, or might reasonably be taken to be, for therapeutic use;

(c) included in a class of appliances the sole or principal use of which is, or ordinarily is, a use for the purpose of or in connection with measuring or weighing therapeutic goods by the person using or administering those goods; or

(d) represented to be, or might reasonably be taken to be, for a use of the kind referred to in paragraph (c),

and includes an appliance the subject of a notice under section 6(b)(i), but does not include an appliance the subject of a notice under section 6(b)(ii);

"therapeutic goods" means a therapeutic substance or therapeutic appliance;

"therapeutic substance" means a substance that is -

(a) included in a class of substances the sole or principal use of which is, or ordinarily is, a therapeutic use;

(b) represented to be, or might reasonably be taken to be, for therapeutic use;

(c) represented to be, or might reasonably be taken to be, for use as an ingredient, or the sole ingredient, in the manufacture of a substance referred to in paragraph (a) or (b), whether or not the substance that is so represented or might reasonably be so taken is to be itself the subject of manufacture or of further manufacture; or

(d) included in a class of substances the sole or principal use of which is, or ordinarily is, a use of the kind referred to in paragraph (c),

and includes -

(e) a gelatin capsule or other substance enclosing a substance referred to in paragraph (a), (b), (c) or (d), where the capsule or other substance is intended to be consumed or otherwise administered together with the substance so referred to; and

(f) a substance the subject of a notice under section 6(a)(i),

but does not include -

(g) an article of food; or

(h) a substance the subject of a notice under section 6(a)(ii);

"therapeutic use" means a use for the purpose of or in connection with -

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

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

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

(d) destroying or inhibiting micro-organisms that may be harmful to,

man or animals;

"vending machine" means a machine or mechanical device that is used or capable of being used for the purpose of selling or supplying goods without the personal manipulation or attention of the seller or supplier or his employee or other agent at the time of the sale or supply;

"veterinary surgeon" means a registered veterinary surgeon within the meaning of the *Veterinary Surgeons Act*;

"wholesale dealing" -

(a) means the sale or supply by a wholesale dealer in the ordinary course of his business to persons authorized by or under the *Poisons and Dangerous Drugs Act* or the *Pharmacy Act* to be in possession of or to sell therapeutic goods or a class of therapeutic goods; and

(b) includes the sale or supply to other persons in wholesale quantities in the ordinary course of that business for use in a public institution or in connection with a prescribed profession, business, trade or industry carried on by a person who requires therapeutic goods or a class of therapeutic goods for use, but not for resale, in connection with his profession, business, trade or industry.

(2) For the purposes of this Act, a substance or appliance shall be deemed to be represented -

(a) as suitable for therapeutic use or cosmetic use where it is, whether by reason of the way in which it is put up or for any other reason, likely to be taken to be for therapeutic use or cosmetic use; and

(b) to consist, either in whole or in part, of a particular substance or appliance where -

(i) the substance or appliance bears a name or description that is -

(A) or is likely to be taken for, a description; or

(B) likely to cause the substance or appliance to be taken to consist, in whole or in part,

of the substance or appliance;

(ii) the Minister is informed, in pursuance of a notice served under section 61, that the substance or appliance consists, in whole or in part, of the substance or appliance; or

(iii) the substance or appliance is otherwise represented by writing or otherwise, or otherwise purports, to consist in whole or in part of the substance or appliance.

(3) For the purposes of subsection (2), a substance or appliance shall be deemed to bear a name or description where the name or description, as the case may be, is set out on the substance or appliance or -

(a) a container or package containing;

(b) a label affixed or attached to; or

(c) a label affixed or attached to, or inserted in, a container or package containing,

the substance or appliance.

(4) For the purposes of the definition of "goods for veterinary use only" in subsection (1), goods are deemed to bear particulars where those particulars are set out on -

(a) those goods or a part of those goods;

(b) a container or package in which those goods are, or a part of those goods is, contained;

(c) a label attached to those goods or a part of those goods; or

(d) a label attached to or inserted in a container or package in which those goods are, or a part of those goods is, contained.

5. THIS ACT TO PREVAIL

This Act is in addition to, and not in derogation of -

(a) the *Pharmacy Act*;

(b) the *Poisons and Dangerous Drugs Act*;

(c) the *Public Health Act*; and

(d) the *Stock Foods Act*,

but, where a provision of this Act is inconsistent or in conflict with a provision of any of those Acts, this Act, to the extent of the inconsistency or conflict, prevails.

PART II - ADMINISTRATION

Division 1 - Notices by Minister

6. NOTICE IN RELATION TO CERTAIN GOODS

The Minister may, by notice in the *Gazette*, declare -

(a) a substance specified or described in the notice -

(i) to be a therapeutic substance;

(ii) not to be a therapeutic substance;

(iii) to be a cosmetic;

(iv) not to be a cosmetic; or

(v) to be an article of food; or

(b) an appliance specified or described in the notice -

(i) to be a therapeutic appliance; or

(ii) not to be a therapeutic appliance,

where he is of the opinion that, but for the notice, doubt would exist or may arise as to whether or not the substance or appliance is a therapeutic substance or therapeutic appliance or cosmetic or is an article of food, as the case may be.

7. MINISTER MAY DECLARE PUBLIC INSTITUTION

The Minister may, by notice in the *Gazette*, declare a nursing institution, within the meaning of the *Private Hospitals and Nursing Homes Act*, to be a public institution for the purposes of this Act.

8. EXEMPTION

The Minister may, by notice in the *Gazette*, exempt persons, therapeutic goods, cosmetics or a class of them specified or described in the notice from the provisions of this Act or such of them as are specified in the notice.

Division 2 - Inspectors

9. APPOINTMENT OF INSPECTORS, &c.

(1) The Minister may, by notice in the *Gazette*, appoint a person who -

(a) in the opinion of the Minister, is competent; and

(b) is an employee within the meaning of the *Public Service Act*,

to be an inspector for the purposes of this Act.

(2) The Administrator may enter into an arrangement with the Governor-General of the Commonwealth for the exercise and performance, by an officer of the Commonwealth or an authority of the Commonwealth, of the powers, duties or functions under this Act of an inspector.

(3) An arrangement under this section may make provision for all or any matters necessary or convenient to be provided for or incidental to the carrying out of the arrangement referred to in subsection (2), and shall provide for the variation of the arrangement and for termination by the Administrator at any time.

(4) The powers, duties and functions under this Act of an inspector may be exercised or performed by an officer of the Commonwealth or an authority of the Commonwealth provided for by or under an arrangement under this section.

(5) The Minister shall furnish to each person who is an inspector by virtue of an -

(a) appointment under subsection (1); or

(b) arrangement under this section,

a certificate in the approved from of his appointment as an inspector.

10. POWERS OF INSPECTORS

(1) For the purposes of this section, "goods" means goods that -

(a) are -

(i) therapeutic goods or cosmetics; and

(ii) for sale or are, whether or not the goods are to be the subject of further manufacture, intended for sale; or

(b) an inspector believes, on reasonable grounds, to be goods referred to in paragraph (a),

but does not apply to or in relation to goods or classes of goods prescribed as exempt from the operation of this section.

(2) An inspector may, in order to ascertain whether, at a particular time, this Act is or was being complied with or whether a contravention of this Act is occurring or has occurred, on production of his certificate of appointment -

(a) enter, at a reasonable time, premises that he believes, on reasonable grounds, are used for or in relation to the manufacture, distribution, conveyance, storage, handling, sale or supply of goods and inspect and search those premises;

(b) require the production of, and inspect and make copies of, or take extracts from, books or documents relating to the manufacture of or dealings in goods that are kept or that he finds on those premises;

(c) require the production of goods that are kept or that he finds on those premises;

(d) open and examine a container or package that is kept or that he finds on those premises and that he believes, on reasonable grounds, may contain goods;

(e) examine goods that are kept or that he finds on those premises;

(f) procure and remove for analysis samples of goods that are kept or that he finds on those premises; and

(g) subject to subsection (3), seize goods that are kept or that he finds on those premises.

(3) Without affecting the powers under subsection (2)(f) of an inspector, an inspector shall not seize under subsection (2)(g) goods -

(a) unless the inspector believes, on reasonable grounds, that, in relation to those goods, a contravention of or a failure to comply with this Act is occurring or has occurred at a particular time; and

(b) in the case of goods that are in the possession, care, custody or control of a manufacturer of those goods, unless the inspector also believes, on reasonable grounds, that those goods are for sale or are, without further manufacture other than packaging or labelling, intended for sale.

11. LIABILITY FOR ACTS

Where the Minister (including a delegate of the Minister) or an inspector does an act or makes an omission in good faith in -

(a) the exercise or purported exercise of a power; or

(b) the performance or purported performance of a duty or function,

under this Act for the purpose of giving effect to the provisions of this Act or for discharging an obligation placed on him by this Act, no action, claim or demand, either civil or criminal, in respect of the act or omission lies, or shall be commenced or allowed, against the Territory, the Minister (including a delegate of the Minister) or an inspector.

Division 3 - Analysts

12. APPOINTMENT OF ANALYSTS

(1) The Minister may, by notice in the *Gazette*, appoint a person who -

(a) in the opinion of the Minister, is competent; and

(b) is not directly or indirectly engaged in or connected with the manufacture or sale of therapeutic goods or cosmetics,

to be an analyst for the purposes of this Act.

(2) A notice under subsection (1) shall include the address of the laboratory or residence of the person to whom the notice relates.

13. ANNUAL REPORT BY ANALYSTS

An analyst (including a person the subject of a notice under section 14(1)) shall, on or before 31 December in each year, report to the Minister the number of samples of therapeutic goods and cosmetics analysed under or for the purposes of this Act by him during the 12 months ending on the preceding 30 June and shall specify in the report the result of each such analysis.

14. TERMINATION OR SUSPENSION OF ANALYSTS

(1) Where an analyst has contravened or failed to comply with this Act or the Regulations in relation to a prescribed method of analysis, the Minister may, where he is satisfied that the contravention or failure has been wilful, by notice in writing served on the analyst -

(a) terminate; or

(b) suspend, for the period specified in the notice,

his appointment as an analyst.

(2) Subject to section 13, where a person receives a notice under subsection (1) terminating or suspending his appointment as an analyst, he shall not -

(a) where his appointment has been terminated - commencing upon his receipt of the notice; and

(b) where his appointment has been suspended - for the period of suspension specified in the notice,

exercise the powers or perform the duties or functions conferred or imposed under this Act upon an analyst.

Division 4 - Duties of Analysts and Inspectors

15. DUTIES OF ANALYSTS AND INSPECTORS

(1) Where, under this Act, therapeutic goods or cosmetics are submitted or transmitted by -

(a) an inspector by whom the therapeutic goods or cosmetics have been procured or seized; or

(b) a person who, under section 27, is entitled to have the therapeutic goods or cosmetics analysed,

to an analyst for analysis, the analyst shall, as soon as practicable after that receipt, carry out the analysis and prepare a certificate in the prescribed form of the result of the analysis.

(2) Where, under section 10(2)(d) or (e), an inspector examines stocks of therapeutic goods or cosmetics, he shall, as soon as practicable after the completion of the examination, prepare a certificate in the prescribed form of the result of the examination.

PART III - LICENCES AND PERMITS

16. APPLICATION FOR LICENCE

(1) This section applies where regulations made under sections 43, 44 or 45 require a licence to be held to manufacture or sell therapeutic goods or cosmetics.

(2) A person may make an application in the approved form accompanied by the prescribed fee to the Minister for a licence to -

(a) manufacture on premises specified in the application -

(i) therapeutic goods generally or a specified class or classes of them; or

(ii) cosmetics generally or a specified class or classes of them;

(b) sell by wholesale -

(i) therapeutic goods generally or a specified class or classes of them; or

(ii) cosmetics generally or a specified class or classes of them; or

(c) sell by retail therapeutic appliances generally or a specified class or classes of them.

17. GRANT OF LICENCE

(1) The Minister shall determine an application under section 16 by a person for a licence by -

(a) granting; or

(b) refusing to grant,

a licence to the person.

(2) Where the Minister refuses under subsection (1)(b) to grant a licence to a person who has made an application under section 16 for the licence, the prescribed fee referred to in that section accompanying the application shall be refunded to the person.

18. APPLICATION, &c., FOR PERMIT TO HAWK

(1) This section applies where regulations made under section 48 require a permit to be held to hawk therapeutic goods.

(2) A person may make an application in the approved form accompanied by the prescribed fee to the Minister for a permit to hawk therapeutic goods generally or a specified class or classes of them.

(3) The Minister shall determine an application under subsection (1) by a person for a permit by -

(a) granting; or

(b) refusing to grant,

a permit to the person.

(4) Where the Minister refuses under subsection (3)(b) to grant a permit to a person who has made an application under subsection (1) for the permit, the prescribed fee referred to in subsection (2) accompanying the application shall be refunded to the person.

19. TERMS AND CONDITIONS OF LICENCES AND PERMITS

(1) A licence or permit shall be in the approved form and shall, subject to section 20, be subject to the prescribed terms and conditions applicable to it.

(2) A licence or permit shall, subject to the conditions endorsed on it, remain in force -

(a) for a period not exceeding 12 months after the date of its issue; or

(b) until it is -

(i) cancelled or suspended under section 21; or

(ii) surrendered under section 22,

whichever first occurs.

(3) The holder of a licence or permit may make an application for the renewal of the licence or permit as if the application were -

(a) in the case of the holder of a licence - an application under section 16 for a licence; and

(b) in the case of the holder of a permit - an application under section 18(1) for a permit.

20. VARIATION, &c., OF CONDITIONS OF LICENCES AND PERMITS

(1) The Minister may, by notice in writing served on the holder of a licence or permit -

(a) vary or amend; or

(b) add to or revoke,

a condition of the licence or permit.

(2) The holder of a licence or permit may make an application in the approved form to the Minister to -

(a) vary or amend; or

(b) add to or revoke,

a condition of the licence or permit.

(3) The Minister shall determine an application under subsection (2) by the holder of a licence or permit to -

(a) vary or amend; or

(b) add to or revoke,

a condition of the licence or permit by serving on the holder a notice in writing -

(c) approving; or

(d) refusing to approve,

the variation or amendment, or the addition to or revocation, as the case may be, of the condition.

(4) A notice under subsection (1) or (3)(c) shall have the effect of a condition endorsed on the licence or permit to which the notice relates.

21. CANCELLATION OR SUSPENSION OF LICENCES AND PERMITS

(1) Where the holder of a licence or permit -

(a) contravenes or fails to comply with a condition of his licence or permit; or

(b) is convicted of an offence against this Act or the Regulations,

the Minister may, by notice in writing served on the holder, cancel or suspend the licence or permit.

(2) Where the holder of a licence or permit receives a notice under subsection (1), he shall, as soon as practicable after that receipt, return the licence or permit to the Minister.

22. SURRENDER OF LICENCES AND PERMITS

The holder of a licence or permit may, at any time, surrender his licence or permit by notice in writing, accompanied by the licence or permit, to the Minister.

PART IV - SAMPLES AND ANALYSIS, &c.

23. DEFINITION

For the purposes of this Part, unless the contrary intention appears, "seller" means -

(a) a person who is engaged in the business of selling or manufacturing therapeutic goods or cosmetics;

(b) an agent or servant of the person referred to in paragraph (a); or

(c) a person in charge of therapeutic goods or cosmetics, whether in transit or otherwise.

24. PROCURING SAMPLES FOR ANALYSIS

(1) Subject to subsection (5), an inspector shall, in procuring under section 10(2)(f) a sample of therapeutic goods or cosmetics, pay, or tender payment of, an amount equal to the current market value of the sample to the person from whom the sample is procured.

(2) An inspector may require a seller, whether the seller is in transit or otherwise, to show, and permit the inspection of, a container or package in which therapeutic goods or cosmetics are contained, and may take or draw, or require the seller to take or draw, from the container or package a sample.

(3) Where therapeutic goods or cosmetics are contained for retail sale in a closed package, a person shall not be required under this section to sell to an inspector less than the whole of the contents of the package.

(4) Where an inspector, in pursuance of subsection (1), pays, or tenders payment, to a seller the current market value or the rate prescribed, if any, for a sample of therapeutic goods or cosmetics, the seller shall sell the sample to the inspector.

(5) Where a rate has been prescribed for the payment of a sample of particular therapeutic goods or cosmetics, or a class or classes of them, it is not necessary for an inspector to pay, or tender payment of, an amount higher than the rate so prescribed for such a sample.

(6) Subject to subsection (7), a person may require an inspector to purchase a sample of therapeutic goods or cosmetics and submit the sample for analysis.

(7) An inspector shall not purchase a sample of therapeutic goods or cosmetics in pursuance of a requirement under subsection (6) by a person unless the person has paid -

(a) the prescribed fee; and

(b) the cost of the sample.

25. ANALYSIS OF GOODS PROCURED BY INSPECTOR

(1) Where a sample is procured under section 10(2)(f) by an inspector for the purposes of analysis, the inspector shall -

(a) immediately inform the person from whom he procured the sample of the purpose for which he procured it;

(b) except as otherwise provided in this Act, divide the sample into 3 portions of equal, or approximately equal, quantity and securely close or fasten up each portion in a separate container or package, as may be appropriate to its nature, and seal each one;

(c) clearly and legibly mark each container or package with a distinctive mark of identification;

(d) deliver or, where delivery is not taken, tender to the person from whom he procured the sample one portion so marked;

(e) retain one portion;

(f) deliver or transmit to an analyst the third portion as soon as is reasonably practicable; and

(g) transmit a copy of the certificate of analysis of the portion referred to in paragraph (f) to -

(i) the person, if any, against whom the inspector intends to take proceedings in respect; and

(ii) the seller,

of the sample.

(2) Where therapeutic goods or cosmetics are sold in a container or package or consist of a therapeutic appliance, an inspector who procures under this Act a sample of them may procure 3 of the containers or packages each purporting to contain the same kind of goods or cosmetics and bearing the same label or, as the case may be, 3 of the appliances each bearing an identical label, and in that case each container or package or appliance so procured shall be deemed to be one such portion as is referred to in subsection (1) and no division of them is required.

(3) The Regulations may prescribe the procedure to be followed in respect of a particular kind of therapeutic goods or cosmetics and that procedure may be in addition to or in substitution for the procedure provided in subsections (1) and (2) to such extent as prescribed.

(4) Subject to subsection (5), in proceedings under this Act in respect of therapeutic goods or cosmetics a sample of which has been submitted to an analyst as provided in this section, the court before which the proceedings are heard shall not receive the certificate of analysis of them as evidence in pursuance of section 57 unless it is satisfied that this section has been complied with.

(5) In proceedings under this Act in respect of therapeutic goods or cosmetics bought in the usual course of business by a person other than an inspector, where it is provided that the sample of the therapeutic goods or cosmetics submitted for analysis was in the same state when received by the analyst as when so bought, the certificate of analysis of them may be received as evidence without proof of compliance with this section.

26. FORWARDING OF SAMPLE BY POST

Where -

(a) a person buys; or

(b) an inspector procures or seizes under this Act,

a sample of therapeutic goods or cosmetics at a place outside a radius of 25 km from the General Post Office at Darwin, the sample may be forwarded by post or in another convenient way to an analyst, and a certificate of the analyst that, on receipt of the sample by him, the seal on the container or package in which the sample was contained was unbroken, is evidence of the sample being identical with the therapeutic goods or cosmetics from which the sample was taken.

27. RIGHT OF OWNER OR BUYER TO HAVE GOODS ANALYSED

(1) The owner or buyer of therapeutic goods or cosmetics may, on payment of the prescribed fee, have the goods or cosmetics analysed by an analyst and receive from the analyst who analysed the goods or cosmetics the certificate of analysis of them.

(2) Where a method of analysis has been prescribed for the analysis of a particular kind of therapeutic goods or cosmetics, an analyst shall, in his analysis of those therapeutic goods or cosmetics, follow the method and so declare this in the certificate of analysis of them.

(3) A copy of a certificate of analysis of therapeutic goods or cosmetics, made at the request of -

(a) an owner or buyer of those goods or cosmetics; or

(b) an inspector,

shall be supplied by the analyst who prepared the certificate to -

(c) the person from whom those goods or cosmetics were taken or obtained; and

(d) the manufacturer, or his agent in the Territory, of those goods or cosmetics.

28. COPY OF INSPECTOR'S CERTIFICATE IN CERTAIN CASES

A copy of a certificate of examination shall, on demand, be supplied by the inspector who prepared the certificate to -

(a) the person whose stocks of therapeutic goods or cosmetics are the subject of the certificate; or

(b) the person's agent in the Territory.

29. ADDITIONAL COPIES OF CERTIFICATES

Where a copy of a certificate of analysis or certificate of examination is supplied under, respectively, section 27(3) or 28 to a person, the analyst or the inspector, as the case may be, who supplied the copy of the certificate shall, on demand, supply to the person a reasonable number of additional copies of the certificate.

30. ANALYSIS NOT TO BE REFERRED TO FOR TRADE PURPOSES, &c.

A person shall not, for trade purposes or advertisement, refer to an analysis made in pursuance of this Part.

Penalty: $200.

PART V - DEALINGS WITH SEIZED GOODS, &c.

31. RELEASE OF SEIZED GOODS

(1) Subject to subsection (5), an inspector shall, as soon as practicable after the expiration of the period prescribed for the detention of seized goods, release those goods unless -

(a) a court orders under section 32 that the goods be forfeited to the Territory; or

(b) the forfeiture to the Territory of the goods is consented to under section 35.

(2) An inspector may release seized goods before the expiration of the period referred to in subsection (1).

(3) The release under subsection (1) or (2) of seized goods shall be made to the owner of those goods or the person in whose possession, care, custody or control they were at the time of their seizure.

(4) Nothing in this section requires the release of seized goods or part of them that have been damaged or destroyed in the course of an analysis.

(5) A court may, in a particular case, extend the period referred to in subsection (1).

32. ORDER THAT GOODS BE FORFEITED

(1) A court may order that, on the expiration of a period specified in the order, seized goods specified in the order shall be forfeited to the Territory.

(2) An order under subsection (1) does not have effect in respect of seized goods that have been released under section 31(1) or (2).

33. ORDER THAT EXPENSES BE PAID

A court may order that a person specified in the order pay -

(a) an amount that the court considers the reasonable expenses of seizing, forfeiting and disposing under this Act of goods and, where those goods were submitted or transmitted in pursuance of section 15(1) by an inspector for analysis, the reasonable expenses of the analysis; or

(b) $200,

whichever amount is the lesser.

34. STORAGE OF AND INTERFERENCE WITH SEIZED GOODS

(1) Subject to the directions of the Minister, seized goods may, at the option of the inspector who seized them, be -

(a) kept or stored on the premises on which they were seized; or

(b) taken to, and kept or stored at, such other place as that inspector determines,

until they are released or disposed of under this Act.

(2) A person shall not, without the authority of the Minister or an inspector, remove, alter or interfere with seized goods.

35. FORFEITURE OF SEIZED GOODS WITH CONSENT

The owner of seized goods or the person in whose possession, care, custody or control they were at the time of their seizure, may consent in writing to their forfeiture to the Territory, and, where such consent is given, the goods are forfeited accordingly.

36. DISPOSAL OF FORFEITED GOODS

Goods forfeited under this Act to the Territory may be disposed of in such manner as the Minister directs, either generally or in a particular case or class of cases.

PART VI - ADVERTISING, &c.

37. CERTAIN REPRESENTATIONS IN ADVERTISEMENTS PROHIBITED

(1) Subject to subsection (4), a person shall not publish an advertisement in relation to -

(a) therapeutic goods where it contains a prescribed prohibited representation;

(b) prescribed therapeutic goods or a prescribed article of food where it contains a prescribed prohibited representation;

(c) prescribed therapeutic goods or a prescribed article of food unless it contains a prescribed representation; or

(d) prescribed therapeutic goods or a prescribed article of food where it contains a representation other than a prescribed representation.

(2) A person shall not publish an advertisement that contains a representation where the advertisement contains a comment, reference or explanation that expressly or impliedly contradicts, qualifies or modifies a prescribed representation.

(3) The Regulations may prescribe, in relation to prescribed therapeutic goods or a prescribed article of food or all therapeutic goods or all articles of food, a representation for the purposes of subsection (1)(a), (b) or (c) notwithstanding that the Regulations prescribe a representation in relation to those therapeutic goods or that article or those articles of food for the purposes of all or any of the paragraphs in subsection (1).

(4) Nothing in subsection (1) applies to or in relation to a representation contained in an advertisement that is contained in a journal the circulation of which is intended to be limited to persons who are -

(a) medical practitioners, pharmacists, dentists, veterinary surgeons or nurses; or

(b) engaged in the business of selling therapeutic goods by wholesale,

or that is contained in another document that is intended to be published exclusively for such persons.

(5) Nothing in this section affects the operation of this Act in relation to standards for the labelling of therapeutic goods.

(6) In this section, "representation", in relation to therapeutic goods or an article of food, means a representation, whether express or implied, in relation to the use or consumption of those goods or that article for the purpose of or in connection with -

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

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

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

(d) destroying or inhibiting micro-organisms that may be harmful to man or animals.

38. ADVERTISEMENTS TO CONTAIN NAME, &c.

(1) Except as prescribed, a person who publishes an advertisement in relation to therapeutic goods shall include in the advertisement -

(a) the name and address of the person authorizing the publication of the advertisement; and

(b) the prescribed information.

(2) Nothing in this section -

(a) requires the inclusion of the name and address of the person authorizing publication in an advertisement that is published orally or by means of producing or transmitting light or sound; or

(b) affects the operation of this Act in relation to standards for the labelling of therapeutic goods.

39. FALSE REPRESENTATIONS, &c., PROHIBITED

(1) Where the Minister is of the opinion that a representation, where made in respect of therapeutic goods or cosmetics, would be false or misleading, he may, by notice in writing served on a person specified or described in the notice, prohibit the person from publishing an advertisement that contains the representation, whether express or implied, made in relation to those goods or cosmetics.

(2) Where the Minister is of the opinion that the name of therapeutic goods or cosmetics, where sold or advertised under the name, would be misleading, he may, by notice in writing served on a person specified or described in the notice, prohibit the person from selling or supplying those goods or cosmetics under the name or from publishing an advertisement advertising those goods or cosmetics under the name.

(3) A notice under this section takes effect 7 days after the date of service of the notice.

(4) A person shall not -

(a) publish an advertisement; or

(b) sell therapeutic goods or cosmetics,

in contravention of a notice under this section.

(5) A notice may be made under subsection (1) in relation to a representation whether or not that representation may be made under section 37.

(6) A person who is guilty of an offence against section 37 or 38 in relation to a representation contained in an advertisement is not liable to conviction for an offence under the other of those sections in respect of the same representation contained in the advertisement.

40. EXAMINATION, &c., OF THERAPEUTIC GOODS THAT HAVE BEEN ADVERTISED

(1) The Minister may cause therapeutic goods or cosmetics in respect of which an advertisement has been published to be examined for the purpose of ascertaining the composition and properties of those goods or cosmetics, and shall cause the results of the examination to be compared with the advertisement that relates to those goods or cosmetics and the price at which those goods or cosmetics are sold.

(2) A person carrying out an examination and comparison under subsection (1) shall prepare and forward to the Minister a report on the matter, which may include a comment which the person considers to be in the public interest.

(3) On receipt of a report under this section, the Minister may cause the report to be published in the *Gazette* and in a newspaper circulating in the Territory or to be distributed to the public, and no action lies in respect of the publication.

(4) A proprietor or manager of a newspaper may republish in the newspaper a report that has been published under subsection (3) and no action lies in respect of the republication.

41. ADVERTISEMENT OR SALE OF CERTAIN GOODS PROHIBITED

The Administrator may, on the recommendation of the Minister, by notice in the *Gazette* and in a newspaper circulating in the Territory, prohibit, after the date specified in the notice -

(a) the advertising, sale or supply of therapeutic goods that, in the opinion of the Minister, are injurious to life or health or that by reason of their inactivity or inefficiency are useless for the advertised purposes of cure; or

(b) the sale of a substance or compound as a disinfectant, germicide, antiseptic or preservative.

(2) A person shall not -

(a) advertise, sell or supply therapeutic goods in contravention of a notice under subsection (1)(a);

(b) being the proprietor or manager of a newspaper, publish an advertisement that is prohibited by a notice under subsection (1)(a);

(c) print or distribute an advertisement that is prohibited by a notice under subsection (1)(a); or

(d) sell a substance or compound the sale of which is prohibited by a notice under subsection (1)(b).

42. LABELLING OF CERTAIN SUBSTANCES, &c.

(1) The Minister may, by notice in the *Gazette*, require that, in relation to a substance or compound that is sold or intended to be sold as a disinfectant, germicide, antiseptic or preservative, such information and directions as he thinks fit shall be set out on a statement or label written on or attached to a container or package containing the substance or compound.

(2) A person shall not sell a substance or compound the subject of a notice under subsection (1) in contravention of the notice.

PART VII - OFFENCES

43. MANUFACTURE OF CERTAIN SUBSTANCES, &c., PROHIBITED EXCEPT UNDER LICENCE

(1) The Regulations may prescribe -

(a) therapeutic substances or classes of them; and

(b) cosmetics or classes of them,

to which subsection (2) applies but, in any case, that subsection does not apply to or in relation to therapeutic substances that are manufactured by -

(c) a medical practitioner or dentist for use in the treatment of a patient who is under the care of the medical practitioner or dentist; or

(d) a pharmacist on -

(i) premises on which the business of a pharmacist is carried on in open shop; or

(ii) the premises of a public institution,

for sale or supply, otherwise than by wholesale, on or from those premises.

(2) A person who -

(a) is the occupier, or has the control, of premises on which therapeutic goods or cosmetics or a class of therapeutic goods or cosmetics to which this section applies are manufactured for sale or supply to other persons; or

(b) on premises manufactures therapeutic goods or cosmetics for sale or supply to other persons,

is guilty of an offence unless the manufacture of those goods or cosmetics on those premises is authorized under a licence.

44. SALE BY WHOLESALE OF CERTAIN GOODS, &c., PROHIBITED EXCEPT UNDER LICENCE

(1) The Regulations may prescribe -

(a) therapeutic goods or classes of them; and

(b) cosmetics or classes of them,

to which subsection (2) applies.

(2) A person who sells by wholesale therapeutic goods or cosmetics, or a class of therapeutic goods or cosmetics, to which this section applies is guilty of an offence unless the sale of them by wholesale is authorized under a licence.

45. SALE BY RETAIL OF CERTAIN APPLIANCES PROHIBITED EXCEPT UNDER LICENCE

(1) The Regulations may prescribe appliances or classes of them to which subsection (2) applies.

(2) A person who sells by retail an appliance or class of appliances to which this section applies is guilty of an offence unless the sale by retail of the appliance or class of appliances is authorized under a licence.

46. SUBSTANCES, &c., SHALL COMPLY WITH STANDARDS

(1) A person shall not knowingly sell or supply to another person therapeutic goods or cosmetics that do not conform to a standard that is applicable to them.

Penalty: $200 or imprisonment for 6 months.

(2) In a prosecution for an offence against subsection (1), it is a defence where the person charged with the offence proves that at the time of the sale or supply of the therapeutic goods or cosmetics to which the offence relates, he had no reason to believe, and did not in fact believe, that the therapeutic goods or cosmetics did not conform to the standard to which the offence relates, and where the Regulations -

(a) make provision for or in relation to the determination of the person whose duty it is to ensure conformity with the standard in relation to the therapeutic goods or cosmetics, that it was not the defendant's duty to ensure conformity with that standard; or

(b) do not so provide, that it was not reasonable to expect that the defendant should have been able to ensure conformity with the standard in so far as the ensuring of conformity with the standard related to acts, matters or things outside his control.

47. SELLING BY VENDING MACHINES RESTRICTED

(1) A person shall not, except with the approval in writing of the Chief Medical Officer within the meaning of the *Public Health Act* -

(a) whether on or about his premises or elsewhere -

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

(ii) sell or supply such goods by means of a vending machine;

(b) permit or suffer a vending machine designed for the sale of therapeutic goods to be installed on his premises or on premises under his control;

(c) place therapeutic goods or permit or suffer therapeutic goods to be placed in a vending machine on his premises or on premises under his control; or

(d) permit or suffer a person to buy or be supplied with or otherwise obtain therapeutic goods by means of a vending machine on the premises of, or under the control of, the first-mentioned person.

Penalty: $200 or imprisonment for 6 months and $20 for each day during which the offence continues.

(2) Subsection (1) does not apply to the installation and use of a vending machine to supply toothpaste, toothbrushes, soap (whether in solid or liquid form), condoms, handcream, razors or razor blades, or any kind or class of therapeutic goods that the Chief Medical Officer, by notice in the *Gazette*, has declared to be therapeutic goods to which subsection (1) does not apply.

48. HAWKING OF THERAPEUTIC GOODS PROHIBITED

(1) A person shall not, except under the authority of a permit, hawk therapeutic goods.

(2) Subsection (1) does not apply to or in relation to the free distribution of clinical samples of therapeutic goods, other than Schedule 8 substances within the meaning of the *Poisons and Dangerous Drugs Act*, to medical practitioners, pharmacists, dentists or veterinary surgeons by persons engaged in the manufacture of, or dealing in, those goods, where the distribution is made to the medical practitioner, pharmacist, dentist or veterinary surgeon by leaving them at his place of business or by posting, by registered post, a package containing the goods addressed to him.

49. OBSTRUCTION OF INSPECTOR

A person shall not -

(a) hinder, obstruct or assault an inspector exercising or attempting to exercise his powers, or performing or attempting to perform his duties or functions, under this Act; or

(b) fail to comply with a lawful direction given under this Act by an inspector.

50. OFFENCE BY BODY CORPORATE

(1) Where a body corporate is guilty of an offence against this Act or the Regulations, an officer of the body corporate who was in any way, by act or omission, directly or indirectly, knowingly concerned in or party to the commission of the offence is also guilty of that offence.

(2) For the purposes of this section, "officer", in relation to a body corporate, includes -

(a) a director, secretary, executive officer or employee of the body corporate;

(b) a receiver, or a receiver and manager, of the property, or part of the property, of the body corporate;

(c) an official manager or a deputy official manager of the body corporate;

(d) a liquidator of the body corporate; and

(e) a trustee or other person administering a compromise or arrangement made between the body corporate and its creditors.

51. OFFENCES GENERALLY

A person who contravenes or fails to comply with a provision -

(a) of this Act;

(b) the Regulations; or

(c) a notice under this Act within the period specified in the notice,

for which a penalty is not provided by this Act or the Regulations, other than this section, is punishable upon conviction by a fine of $1,000 or imprisonment for 6 months.

52. CONTINUING OFFENCES

A person who has been convicted of contravening or failing to comply with a provision of -

(a) this Act;

(b) the Regulations; or

(c) a notice under this Act within the period specified in the notice,

is guilty of a further offence against this Act or the Regulations where the contravention or failure to comply continues (notwithstanding that the period has elapsed) after he has been convicted and upon conviction of the further offence is punishable by a penalty of $50 for each day during which the offence continues.

53. REGULATORY OFFENCES

An offence of contravening or failing to comply with section 30, 34(2), 37(1), (2), 39(4), 41(2), 42(2), 43(2), 44(2), 45(2), 47, 48(1) or 49 is a regulatory offence.

PART VIII - APPEALS

54. RIGHT OF APPEAL

A person aggrieved by a decision of the Minister -

(a) refusing to grant, renew or vary a licence or permit;

(b) to grant, renew or vary a licence or permit subject to conditions;

(c) to cancel or suspend a licence or permit; or

(d) in relation to the publication or service of -

(i) a notice under section 39, 41(1) or 61(1); or

(ii) a report under section 40(3),

may appeal to a Local Court against the decision.

55. FORM OF APPEAL

An appeal under section 54 shall be -

(a) in writing; and

(b) made not later than 28 days after the date of the decision referred to in that section appealed against.

56. DETERMINATION OF APPEAL

(1) The Local Court to which an appeal under section 54 has been made against a decision referred to in that section -

(a) shall conduct a hearing into the grounds of the decision;

(b) has all the powers, duties and functions of the Minister in relation to the matter the subject of the appeal; and

(c) shall determine the appeal by -

(i) confirming;

(ii) varying, in such manner as it thinks fit;

(iii) substituting its own decision for; or

(iv) disallowing,

the decision.

(2) A determination under subsection (1)(c) shall take effect on the date specified by the Local Court in the determination or, where no date is so specified, on the date of the determination.

PART IX - MISCELLANEOUS

57. INSTITUTION OF PROCEEDINGS

(1) Proceedings for an offence against this Act or the Regulations shall -

(a) be dealt with summarily; and

(b) not be commenced without the consent in writing of the Minister.

(2) Consent under subsection (1)(b) may be proved by the production of a notice in the prescribed form which is purported to be signed by the Minister.

58. FURTHER POWER OF COURT

Where the holder of a licence or permit, or one of his employees, is convicted of an offence against this Act or the Regulations, the court may, in addition to any other penalty imposed upon the licensee, permittee or employee, cancel the licence or permit.

59. CERTIFICATES

Unless the contrary intention appears, in proceedings in respect of an offence against this Act, a certificate purporting to be signed by -

(a) the Minister certifying that a person specified in the certificate was -

(i) or was not the holder of a licence or permit;

(ii) an analyst; or

(iii) an inspector,

on a day, or during a period, specified in the certificate is admissible in evidence and is evidence of the fact so certified;

(b) an inspector certifying that a matter specified in the certificate is a copy of, or extract from, a book or document made or taken under this Act by him is admissible in evidence without production of the book or document; or

(c) an analyst and setting out the results of an analysis under section 25 of therapeutic goods or cosmetics is evidence of the identity of the goods or cosmetics analysed, of the result of the analysis and that the analysis was carried out in such manner, if any, as is specified.

60. DISCLOSURE OF INFORMATION

(1) In proceedings under this Act, a witness on behalf of the prosecution is not obliged to disclose -

(a) the fact that he received information;

(b) the nature of information received by him; or

(c) the name of the person who gave information.

(2) An inspector appearing as a witness in proceedings under this Act is not obliged to produce reports made or received by him confidentially in his official capacity or containing confidential information.

61. MINISTER MAY REQUIRE INFORMATION

(1) The Minister may, by notice in writing served on a person who manufactures in, or imports into, the Territory, or sells or supplies therapeutic goods or cosmetics, require the person to furnish, in writing, to the Minister, or a person nominated by the Minister, within such period, being not less than 14 days after the date of service of the notice, information relating to the goods or cosmetics as specified in the notice.

(2) A notice under subsection (1) may be served on a person whether or not the goods or cosmetics referred to in the notice are goods or cosmetics in relation to which information has previously been furnished.

(3) A person on whom a notice under subsection (1) is served shall comply with the notice within the period specified in the notice.

(4) A person on whom a notice under subsection (1) is served shall not knowingly furnish information that is false or misleading.

62. DELEGATION

(1) The Minister may, by instrument in writing, delegate to a person any of his powers and functions under this Act, other than this power of delegation and his power under section 6 or 9.

(2) A power or function delegated under this section, when exercised or performed by the delegate, shall, for the purposes of this Act, be deemed to have been exercised or performed by the Minister.

(3) A delegation under this section does not prevent the exercise of a power or the performance of a function by the Minister.

63. SERVICE OF DOCUMENTS

A notice or other document which, under this Act, is required or permitted to be served on a person, may be so served by -

(a) handing it or tendering it to;

(b) properly addressing and posting it by pre-paid post to the last-known or usual place of abode or business of; or

(c) leaving it with some person apparently over the age of 16 years at the last-known or usual place of abode or business of,

the person.

64. DETERMINATION OF FEES

The Minister may, by notice in the *Gazette*, determine the fees payable under this Act.

PART X - REGULATIONS, &c.

65. REGULATIONS

(1) The Administrator may make regulations, not inconsistent with this Act, prescribing matters -

(a) required or permitted by this Act to be prescribed; or

(b) necessary or convenient to be prescribed for carrying out or giving effect to this Act,

and in particular for prescribing -

(c) the standards, whether general standards or specific standards, of composition, strength, potency, stability, sterility, quantity, quality, purity and bacteriological content of therapeutic goods or cosmetics or a class of them and defining "general standard" and "specific standard";

(d) the nature and proportion of substances that may be mixed with, or used in, the manufacture, preparation or compounding of therapeutic goods or cosmetics or of a class of them;

(e) the prohibition of the addition to or admixture with therapeutic goods or cosmetics, or a class of them, of specified substances or classes of them;

(f) the packing and labelling of -

(i) therapeutic goods or cosmetics or of a class of them; and

(ii) substances or compounds intended for sale as disinfectant, germicide, antiseptic or preservative,

and the containers and packages containing therapeutic goods or cosmetics or the substances or compounds referred to in subparagraph (ii);

(g) the prohibition of the use in labels attached to or inserted in therapeutic goods and containers and packages containing therapeutic goods and in advertisements relating to therapeutic goods of false or misleading claims, statements, words and devices as to the composition, strength, quality or medicinal values or properties of the goods or of the contents of such containers and packages;

(h) the regulation, control and restriction of the contents of labels and of advertisements relating to therapeutic goods and the prohibition of the use in such labels or advertisements of claims, statements, words and devices indicating or suggesting that the therapeutic goods to which they relate may be used, or are effective, for a particular use;

(j) the inclusion in labels or advertisements of the information specified in the Regulations and prohibiting the omission, in prescribed cases, from such labels or advertisements of prescribed kinds of statements or information;

(k) the measures and precautions to be observed for the purpose of protecting therapeutic goods or cosmetics from deterioration and contamination and the situation, construction, equipment and sanitation of premises and vehicles used for or in connection with the manufacture, preparation, compounding, sale packing, storage and transport of therapeutic goods or cosmetics;

(m) the regulation and control of, and the conditions to be observed in relation to, the manufacture, preparation, compounding, storage and transport of therapeutic goods or cosmetics or of a class of them for the purpose of preventing the deterioration of, or changes in the chemical composition of, those therapeutic goods or cosmetics or that class of therapeutic goods or cosmetics;

(n) the requirement of notice to a prescribed person in respect of therapeutic goods or cosmetics that the manufacturer of the goods or cosmetics or the distributor in the Territory of the goods or cosmetics withdraws from sale or recalls from persons to whom they are sold or supplied and prescribing the person by whom such a notice shall be given and the form and contents of the notice;

(p) the testing and analysis of therapeutic goods or cosmetics;

(q) the sale or prohibition of sale of therapeutic appliances or a class of them;

(r) the exemption of persons, goods, containers and packages in prescribed cases from all or any of the Regulations;

(s) the form of licences and the issue of substitute or duplicate licences;

(t) the form of permits and the issue of substitute or duplicate permits;

(u) the records to be kept by persons engaged in the manufacture, distribution, conveyance, storage, handling, sale or supply of therapeutic goods or cosmetics;

(w) the procedure to be observed by inspectors when seizing and removing portions or samples of therapeutic goods or cosmetics in pursuance of section 10;

(y) the determination of the requirements to which therapeutic goods or cosmetics or a class of them are to conform when sold; and

(z) penalties not exceeding $1,000 for a breach of the Regulations.

(2) A standard for therapeutic goods or cosmetics may relate to -

(a) their composition, strength, potency, stability, purity, quality, construction or other properties;

(b) their quantity;

(c) the manner in which they were manufactured;

(d) their packaging and labelling; or

(e) the manner in which they have been stored, handled or conveyed.

(3) A standard for therapeutic goods or cosmetics may -

(a) prohibit the goods from containing a prescribed substance or a prescribed substance in a prescribed quantity or proportion or in a quantity or proportion that is greater or less than a prescribed quantity or proportion;

(b) require prescribed information or statements to appear on the label, container or package containing the therapeutic goods or cosmetics; or

(c) prohibit prescribed information or statements from appearing on a label, container or package.

(4) A standard for therapeutic goods or cosmetics may require an expiry date, determined in accordance with the Regulations, to be stated on the goods or on a label, container or package.

(5) The Regulations may make provision for or with respect to the determination of the person whose duty it is to ensure conformity with a standard before or at the time of sale or supply of the therapeutic goods or cosmetics to which the standard relates.

(6) The Regulations may -

(a) adopt, either specifically or by reference, either with or without modifications -

(i) standards determined under or prescribed or set out in -

(A) a Commonwealth Act or a regulation or order made under it; or

(B) the *British Pharmacopoeia*, the *British Pharmaceutical Codex*, the *British Veterinary Codex* or other prescribed publication; and

(ii) a method of testing or analysis prescribed under the Commonwealth Act or set out or described in a publication referred to or prescribed under subparagraph (i)(B); and

(b) define the expressions *British Pharmacopoeia*, *British Pharmaceutical Codex* and *British Veterinary Codex* and specify which editions of all or any of those publications are to have effect for the purposes of this Act.

66. PROVISIONS APPLICABLE TO REGULATIONS AND NOTICES

Therapeutic goods or cosmetics may be specified or described in regulations or a notice under this Act by reference to an act, matter or thing specified or described in the regulation or notice and, without affecting the generality of this section, may be specified or described by reference to one or more of -

(a) the common or scientific name or names of the therapeutic goods or cosmetics;

(b) a class of therapeutic goods or cosmetics;

(c) the composition of the therapeutic goods or cosmetics;

(d) the use or intended use of the therapeutic goods or cosmetics;

(e) the purpose for which the therapeutic goods or cosmetics may be used;

(f) a dealing or proposed dealing in or in respect of the therapeutic goods or cosmetics; or

(g) the manner in which the therapeutic goods or cosmetics are packed.

PART XI - TRANSITIONAL

67. TRANSITIONAL

(1) A person who, immediately before the commencement of this Act -

(a) was the occupier, or had the control, of premises on which therapeutic goods or cosmetics were, or a class of therapeutic goods or cosmetics was, manufactured for sale or supply to other persons;

(b) manufactured therapeutic goods or cosmetics for sale or supply to other persons;

(c) sold by wholesale therapeutic goods or cosmetics or a class of therapeutic goods or cosmetics; or

(d) sold by retail an appliance or class of appliance,

and who, before the expiration of 3 months immediately after that commencement, makes an application under section 16 for a licence, may continue to -

(e) occupy or have control of premises referred to in paragraph (a);

(f) manufacture therapeutic goods or cosmetics referred to in paragraph (b);

(g) sell by wholesale therapeutic goods or cosmetics referred to in paragraph (c); or

(h) sell by retail an appliance referred to in paragraph (d),

without a licence to do so until the determination under section 17 of his application or an appeal under section 54 in relation to his application.

(2) A person who, immediately before the commencement of this Act, hawked therapeutic goods and who, before the expiration of 3 months immediately after that commencement, makes an application under section 18(1) for a permit, may continue to hawk therapeutic goods without a permit to do so until the determination under section 18(2) of his application or an appeal under section 54 in relation to his application.