
THERAPEUTIC GOODS AND COSMETICS ACT 1976

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THERAPEUTIC GOODS AND COSMETICS

No. 1 of 1976

AN ACT to regulate the manufacture, distribution, labelling, and advertising of therapeutic goods and certain articles of food, to make provision with respect to standards for therapeutic goods and cosmetics, and to provide for matters incidental thereto.

[5 May 1976]

BE it enacted by His Excellency the Governor of Tasmania, by and with the advice and consent of the Legislative Council and House of Assembly, in Parliament assembled, as follows:—

PART I.

PRELIMINARY.

1—(1) This Act may be cited as the *Therapeutic Goods and Cosmetics Act 1976*. Short title and commencement.

(2) The provisions of this Act shall commence on such days respectively as are fixed by proclamation in relation to each of those provisions.

Interpretation.
Cf. No.14,
1972 (NSW),
s. 4.
No. 81 of 1971
(Tas), s. 3.

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

“advertisement”, in relation to therapeutic goods, means an advertisement that is published—

- (a) in a newspaper or public print that circulates in the State;
- (b) by the distribution through the post or otherwise or by the attachment to, or insertion in, a package or container in which the goods or any other goods are enclosed of any label, handbill, circular, poster, notice, or other written matter;
- (c) by the exhibition of a cinematograph film or of a photograph; or
- (d) by transmission from a radio broadcasting station or television station,

for the purpose of promoting, directly or indirectly, the sale or use of the goods in relation to which it is published;

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

“analyst” means an analyst appointed under section nine, and includes the Government Analyst;

“appliance” includes any—

- (a) instrument, apparatus, contrivance, or device; or
 - (b) component, part, or accessory thereof,
- that is sold, or is represented as suitable, for therapeutic use or cosmetic use;

“article of food” means a substance taken in by the mouth that maintains life and growth;

“automatic 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;

“Commonwealth Act” means the *Therapeutic Goods Act* 1966 of the Commonwealth, and includes that Act as amended from time to time and any Commonwealth Act passed in substitution for that Act;

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

“ cosmetic ” means any goods that—

(a) are, or are included in, a class of goods the sole or principal use of which is, or ordinarily is, a cosmetic use;

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

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

and includes goods in respect of which an order under section fifteen is in force declaring those goods to be a cosmetic, but does not include—

(d) therapeutic goods; or

(e) goods in respect of which an order under that section is in force declaring those goods not to be a cosmetic;

“ court of petty sessions ” means a court held by a magistrate sitting alone in petty session;

“ dentist ” means a certified dentist within the meaning of the *Dentists Act 1919*;

“ expiry date ”, in relation to any goods, means a day after which they may be expected to cease to conform to any standards applicable thereto;

“ goods for veterinary use only ” means goods that—

(a) bear particulars 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 to be intended for human use;

“ inspector ” means a person who is an inspector within the meaning of the *Poisons Act 1971*;

- “ label ” includes any tag, brand, mark, or statement in writing on, or attached to, or used in connection with, a container or package containing therapeutic goods or cosmetics, and “ labelling ” has a corresponding meaning;
- “ magistrate ” means a magistrate within the meaning of the *Magistrates Act* 1969;
- “ medical practitioner ” means a legally-qualified medical practitioner within the meaning of the *Medical Act* 1959;
- “ nurse ” means a person who is the holder of a subsisting certificate of registration under the *Nurses’ Registration Act* 1952;
- “ package ”, in relating to therapeutic goods or cosmetics, includes any means by which those goods or cosmetics may, for transport, for carriage, or for sale, be cased, covered, enclosed, contained, or packed;
- “ pharmaceutical chemist ” means a registered pharmaceutical chemist within the meaning of the *Pharmacy Act* 1908;
- “ public institution ” means—
- (a) a State authority;
 - (b) a public hospital within the meaning of the *Hospitals Act* 1918;
 - (c) the University of Tasmania;
 - (d) a technical college or technical school established under the *Education Act* 1932;
 - (e) the Tasmanian College of Advanced Education; and
 - (f) any other institution or establishment that is not carried on for private gain or reward and is declared by the Minister, by order, to be a public institution for the purposes of this Act;
- “ publish ” includes cause, permit, or suffer to be published;
- “ sell ” means sell, whether by wholesale or retail, and includes—
- (a) offer or expose for sale;
 - (b) keep or have in possession for sale;
 - (c) barter or exchange;
 - (d) deal in or agree to sell;
 - (e) send, forward, deliver, or receive for sale or on sale; and
 - (f) authorize, direct, cause, permit, or suffer any of those acts or things to be done,
- and “ sale ” and “ sold ” have corresponding meanings;

“ State 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 any department, business, undertaking, or institution on behalf of the State;

“ substance ” includes a preparation, an admixture, and a salt or derivative of a substance;

“ supply ” includes offer or agree to supply;

“ therapeutic appliance ” means an appliance that—

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

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

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

and includes any goods in respect of which an order under section fifteen is in force declaring those goods to be a therapeutic appliance, but does not include—

(e) goods for veterinary use only; or

(f) goods in respect of which an order under that section is in force declaring those goods not to be a therapeutic appliance;

“ therapeutic goods ” means a therapeutic substance or therapeutic appliance;

“ therapeutic substance ” means a substance that—

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

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

(c) is 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 paragraph (b) of this

definition, 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) is 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) of this definition,

and includes any—

- (e) gelatin capsule or other substance enclosing a substance referred to in the foregoing paragraphs of this definition, if that capsule or other substance is intended to be consumed or otherwise administered together with the substance so referred to; and

- (f) goods in respect of which an order under section fifteen is in force declaring those goods to be a therapeutic substance,

but does not include—

- (g) an article of food;

- (h) goods for veterinary use only; or

- (i) goods in respect of which an order under that section is in force declaring those goods not to be a therapeutic substance;

“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 man or animal;

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

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

- (d) destroying or inhibiting micro-organisms that may be harmful to man or animal;

“veterinary surgeon” means a registered veterinary surgeon within the meaning of the *Veterinary Act 1918*;

“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 Act* 1971 or the *Pharmacy Act* 1908 to be in possession of or to sell therapeutic goods or any class thereof; 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 any such goods or class of 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 if 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 if—

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

(A) that is, or is likely to be taken for, a description of the substance or appliance; or

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

- (ii) the Minister is informed, in pursuance of a notice under section fifty-three, that the substance or appliance consists, in whole or in part, of that 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 that substance or appliance.

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

- (a) the substance or appliance or any part of the appliance;

- (b) a container or package containing the substance or appliance or any part of the appliance;
- (c) a label affixed or attached to the substance or appliance or any part of the appliance; or
- (d) a label affixed or attached to, or inserted in, a container or package containing the substance or appliance or any part of the appliance.

(4) For the purposes of the definition of “ goods for veterinary use only ” in subsection (1) of this section, goods are deemed to bear any particulars if those particulars are set out on—

- (a) the goods or any part of the goods;
- (b) a container or package in which the goods are, or any part of the goods is, enclosed;
- (c) a label attached to the goods or any part of the goods; or
- (d) a label attached to or inserted in a container or package in which the goods are, or any part of the goods is, enclosed.

Construction
of Act.
Tas., s. 5.

3 The provisions of this Act are in addition to, and not in derogation of, the provisions of—

- (a) the *Pharmacy Act* 1908;
- (b) the *Stock Medicines and Fertilizers Act* 1950;
- (c) the *Public Health Act* 1962;
- (d) the *Pesticides Act* 1968; and
- (e) the *Poisons Act* 1971,

but the provisions of those Acts shall be read subject to the express provisions of this Act, and, where a provision of any of those Acts is inconsistent with a provision of this Act, the last-mentioned provision, to the extent of the inconsistency, prevails.

PART II.

ADMINISTRATION.

Division I—Licences.

Manufacture of
certain
substances and
appliances
prohibited
except under
licence.
N.S.W., ss.12,
14.
Tas., s. 16.

4—(1) After the expiration of the relevant period, a person who—

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

(b) on any 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 the terms of a licence under section seven.

(2) This section applies to such—

(a) therapeutic goods or classes thereof; and

(b) cosmetics or classes thereof,

as may be prescribed, but does not apply to therapeutic goods that are manufactured—

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

(d) by a pharmaceutical chemist—

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

(ii) on the premises of a dispensary that is conducted by a friendly society registered or deemed to be registered under the *Friendly Societies Act* 1888; or

(iii) on the premises of a public institution, for sale or supply, otherwise than by wholesale, on or from those premises.

(3) In this section, “relevant period” means the period of three months beginning on the commencement of this section.

5—(1) After the expiration of the relevant period, a person who sells by wholesale any therapeutic goods or cosmetics, or any class of therapeutic goods or cosmetics, to which this section applies is guilty of an offence unless the sale thereof by wholesale is authorized under the terms of a licence under section seven.

Sale by wholesale of certain goods and appliances prohibited except under licence.
N.S.W., s. 13.

(2) This section applies to such—

(a) therapeutic goods or classes thereof; and

(b) cosmetics or classes thereof,

as may be prescribed.

(3) In this section, “relevant period” means the period of three months beginning on the commencement of this section.

Sale by retail
of certain
appliances
prohibited
except under
licence.

N.S.W., s. 16.

6—(1) After the expiration of the relevant period, a person who sells by retail any appliance or class of appliances that is prescribed as an appliance or a class of appliances to which this section applies is guilty of an offence unless the sale by retail of that appliance or class of appliances is authorized under the terms of a licence under section seven.

(2) In this section “relevant period” means the period of three months beginning on the commencement of this section.

Application
for, and grant
of, licences.
N.S.W., s. 20.

7—(1) The Minister, in his discretion, may, on the application of a person and on payment by that person of the appropriate prescribed fee, grant to that person a licence authorizing—

(a) the manufacture on premises that are specified in the licence of—

- (i) therapeutic goods generally or any specified class or classes thereof; or
- (ii) cosmetics generally or any specified class or classes thereof;

(b) the sale by wholesale of—

- (i) therapeutic goods generally or any specified class or classes thereof; or
- (ii) cosmetics generally or any specified class or classes thereof; or

(c) the sale by retail of therapeutic appliances generally or of any specified class or classes of therapeutic appliances.

(2) A licence—

- (a) shall be in the prescribed form;
- (b) may be granted unconditionally or subject to such conditions and restrictions as the Minister determines and as are specified in the licence or in a notice under subsection (3) of this section; and
- (c) while in force, has effect according to its tenor.

(3) By notice in writing delivered to the holder of a licence under this section or sent to the holder by post by means of the certified mail service, the Minister may—

- (a) attach conditions and restrictions to the licence after it is granted;
- (b) vary or remove a condition or restriction that is specified in the licence; or
- (c) otherwise vary the licence.

(4) A licence under this section remains in force until it is revoked or suspended.

8—(1) The Minister, in his discretion, may—

(a) refuse to grant to a person applying therefor a licence under section seven; or

(b) revoke or suspend a licence granted to a person under that section,

if that person has been, or is, convicted of an offence against this Act or the *Poisons Act 1971* of such a nature that in the opinion of the Minister (having regard to the nature of the offence and to all the circumstances of the case) it would be contrary to the public interest if that person were granted such a licence or if such a licence granted to that person were to continue in force.

(2) Where an application for a licence is refused, the Minister shall cause the fee accompanying the application to be refunded to the applicant.

Division II—Analysts.

9—(1) The Governor may appoint persons who appear to him to possess competent knowledge to be analysts, and may fix the amount of their fees or their remuneration and allowances for expenses.

(2) No person shall be appointed as an analyst if he is directly or indirectly engaged or interested in the manufacture or sale of therapeutic goods or cosmetics.

(3) The Minister shall cause notice to be published in the *Gazette* when an appointment is made under this section stating the address of the place of residence or laboratory of the person appointed.

10 An analyst shall, on or before the thirty-first day of December in each year, report to the Minister the number of samples of therapeutic goods and cosmetics analysed by him under or for the purposes of this Act during the period of twelve months ended on the preceding thirtieth day of June and shall specify the result of each analysis.

11 The Government Analyst has and may exercise all the powers and authorities of an analyst appointed under this Division.

Refusal,
revocation, and
suspension of
licences.

N.S.W., ss.
20, 21.
Tas., s. 17.

Appointment
and
remuneration
of analysts.

N.S.W., s. 39.
Tas., s. 19.

Annual reports
by analysts.

Tas., s. 20.

Powers of the
Government
Analyst.

Tas., s. 21.

Disqualification
of analysts.
Tas., s. 22.

12 An analyst who offends against any of the provisions of this Act with respect to a prescribed method of analysis may, if the Minister is satisfied that the offence has been wilfully committed, be disqualified by the Minister for appointment as an analyst for such period as the Minister thinks fit.

Division III—Inspectors.

Appointment
of inspectors.
Tas., s. 23.

13—(1) The Minister may, by notice in the *Gazette*, appoint such inspectors as he may consider necessary and who in his opinion have suitable qualifications for the administration of this Act.

(2) The Minister shall not appoint a person as an inspector unless the person is—

- (a) an officer or temporary employee within the meaning of the *Public Service Act 1973*;
- (b) a police officer within the meaning of the *Police Regulation Act 1898*; or
- (c) an officer of the Public Service of the Commonwealth or of an authority of the Commonwealth.

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

(4) 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 and shall contain provisions for the variation of the arrangement and a provision to the effect that it may be terminated by the Governor at any time.

(5) While an arrangement under this section is in force, the powers, duties, and functions of an inspector under this Act may be exercised and performed by any officer of the Commonwealth or of an authority of the Commonwealth provided for by or under the arrangement, and a reference in this Act to an inspector shall be read as including a reference to such an officer.

(6) Subject to subsection (1) of this section, a person who is an inspector under the *Poisons Act 1971* shall be deemed to have been appointed as an inspector pursuant to this section.

(7) The Minister shall furnish to a person who is appointed, or who is deemed to have been appointed, as an inspector pursuant to this section or to an arrangement under this section a certificate of that person's appointment.

Division IV—General.

14—(1) Where, under this Act, therapeutic goods or cosmetics are submitted or transmitted to an analyst for analysis by—

Duties of analysts and inspectors. Tas., s. 25.

- (a) an inspector by whom the therapeutic goods or cosmetics have been procured or seized; or
- (b) a person who, under section thirty-four, is entitled to have the therapeutic goods or cosmetics analysed,

the analyst shall carry out the analysis as soon as is practicable after receiving the therapeutic goods or cosmetics and shall, forthwith on the completion of the analysis, prepare a certificate of the result of the analysis in the prescribed form.

(2) Where pursuant to section twenty-three an inspector inspects stocks of any therapeutic goods or cosmetics he shall forthwith after the completion of the inspection prepare a certificate of the results of the inspection in the prescribed form.

15—(1) The Minister may, by order, declare any goods specified or described in the order—

Orders as to certain goods. N.S.W., s. 5.

- (a) to be a therapeutic substance; or
- (b) not to be a therapeutic substance,

if he is of the opinion that, but for the order, doubt would exist or may arise as to whether or not those goods are a therapeutic substance.

(2) The Minister may, by order, declare any goods that are goods specified or described in the order—

- (a) to be a therapeutic appliance; or
- (b) not to be a therapeutic appliance,

if he is of the opinion that, but for the order, doubt would exist or may arise as to whether or not those goods are a therapeutic appliance.

(3) The Minister may, by order, declare any substance that is specified or described in the order—

- (a) to be a cosmetic; or
- (b) not to be a cosmetic,

if he is of the opinion that, but for the order, doubt would exist or may arise as to whether or not that substance is a cosmetic.

16—(1) The Minister may, by order, exempt a person or class of persons, or any therapeutic goods or class of goods, or any cosmetics or class of cosmetics, specified or described in the order from all the provisions of this Act or from such of those provisions as are specified in the order.

Exemptions. N.S.W., s. 6.

(2) An order under this section may be made unconditionally or subject to such conditions as are specified or described therein.

Delegation of functions.
Tas., s. 24.

17—(1) The Minister may, by writing under his hand, delegate—

- (a) to the Director-General of Health Services; or
- (b) on the recommendation of the Director-General, to an officer employed in the Department of Health Services,

all or any of the functions of the Minister under this Act other than—

- (c) the power to make orders under this Act; and
- (d) the power of delegation.

(2) The Minister may, in pursuance of this section, delegate to different persons the functions of the Minister under different provisions of this Act.

(3) A delegation under this section is revocable at the will of the Minister and does not prevent the exercise or performance by him of any of his functions under this Act.

(4) In relation to any function delegated to the Director-General of Health Services or any other officer under this section any reference in this Act to the Minister shall, subject to the terms of the delegation, and so far as the context does not otherwise require, be construed as including a reference to the Director-General or other officer to whom the function is delegated.

PART III.

STANDARDS.

Sale of substances or appliances that are not in conformity with standards.
N.S.W., s. 24.

18 No person shall knowingly sell or supply to another person any—

- (a) therapeutic goods that do not; or
- (b) cosmetic that does not,

conform to a standard that is applicable thereto.

Penalty: Two hundred dollars or imprisonment for six months.

Defence to prosecution under section 18.
N.S.W., s. 25.

19 In a prosecution for an offence arising under section eighteen, it is a defence if the defendant proves that at the time of the sale or supply he had no reason to suppose, and did not in fact suppose, that the therapeutic goods or cosmetic did not conform to the standard, and—

- (a) where the regulations make provision for or with respect to the determination of the person whose duty it is to ensure

conformity with the standard in relation to the therapeutic goods or cosmetic, that it was not the defendant's duty to ensure conformity therewith; or

- (b) where the regulations 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 therewith related to acts, matters, or things outside his control.

PART IV.

ADVERTISEMENTS AND RELATED MATTERS.

- 20**—(1) No person shall publish an advertisement in respect of any—
- (a) prescribed therapeutic goods if it contains a representation;
- (b) therapeutic goods or article of food if it contains a representation prescribed as a prohibited representation;
- (c) prescribed therapeutic goods or prescribed article of food if it contains a representation prescribed as a prohibited representation;
- (d) prescribed therapeutic goods or prescribed article of food unless it contains a representation prescribed as a required representation; or
- (e) prescribed therapeutic goods or prescribed article of food if it contains a representation other than a representation prescribed as a required representation under paragraph (d) of this subsection.

Prohibition of certain representations in advertisements. N.S.W., s. 26.

(2) No person shall publish an advertisement in respect of any prescribed therapeutic goods.

(3) No person shall publish an advertisement that contains a representation if the advertisement contains any comment, reference, or explanation that expressly or impliedly contradicts, qualifies, or modifies a representation prescribed for the purposes of subsection (1) of this section.

(4) The regulations may prescribe in relation to any prescribed therapeutic goods or article of food or all therapeutic goods or articles of food a representation for the purposes of paragraphs (b), (c), and (d) of subsection (1) of this section 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 other or any other of those paragraphs.

(5) A person who is guilty of an offence under either subsection (1) or subsection (3) of this section in respect of a representation contained in an advertisement is not liable to be punished for an offence under the other of those subsections in respect of the same representation contained in that advertisement.

(6) Nothing in subsection (1) or subsection (2) of this section applies in respect of 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 medical practitioners, pharmaceutical chemists, dentists, veterinary surgeons, or nurses or who are engaged in the business of selling therapeutic goods by wholesale or that is contained in any other document that is intended to be published exclusively to or among any such persons.

(7) Nothing in this section affects the operation of any other provision of this Act that relates to standards with respect to the labelling of therapeutic goods.

(8) In this section, “representation”, in relation to any therapeutic goods or article of food, means a representation, whether express or implied, with respect 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 any micro-organisms that may be harmful to man or animal.

Advertisements
to contain
name, address,
&c.
N.S.W., s. 27.

21—(1) Except as provided by the regulations, a person who publishes an advertisement in relation to any therapeutic goods shall include in that advertisement the name and address of the person authorizing the publication of the advertisement and such other information as may be prescribed.

(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 any means of producing or transmitting light or sound; or
- (b) affects the operation of any other provision of this Act that relates to standards with respect to the labelling of therapeutic goods.

22—(1) Where the Minister is of the opinion that a representation, if made in respect of any therapeutic goods or cosmetics, would be false or misleading, he may, by order in writing served on a person specified or described in the order, prohibit that person from publishing any advertisement that contains that representation (whether express or implied) made in respect of any such goods or cosmetics.

Order prohibiting false or misleading representations or names.
N.S.W., s. 28.

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

(3) An order under this section takes effect from a day to be specified therein, which day shall be not earlier than seven days after the service of the notice.

(4) No person shall publish an advertisement in contravention of an order in force under this section.

(5) No person shall sell any therapeutic goods or cosmetics in contravention of an order in force under this section.

(6) An order may be made under this section in relation to a representation whether or not that representation may be made under section twenty.

(7) A person who is guilty of an offence under either section twenty or section twenty-one in respect of a representation contained in an advertisement is not liable to be punished for an offence under the other of those sections in respect of the same representation contained in that advertisement.

PART V.

ENFORCEMENT OF ACT.

Division I—Inspection and seizure of goods.

23—(1) This section applies to goods—

(a) that are—

- (i) therapeutic goods or cosmetics; and
- (ii) are for sale or are (whether or not the goods are to be the subject of further manufacture) intended for sale; or

Powers of inspectors.
N.S.W., s. 30.

- (b) that an inspector believes on reasonable grounds to be such goods as are referred to in paragraph (a) of this subsection,

but does not apply to such goods or classes of goods as are declared by the regulations to be exempted from the operation of this section.

(2) In order to ascertain whether the provisions of this Act are, or were at a particular time, being complied with or whether a contravention of the provisions of this Act is occurring or has occurred at a particular time, an inspector may, on production of his certificate of appointment—

- (a) enter, at any reasonable time, any premises that he believes on reasonable grounds are used for or with respect to the manufacture, distribution, conveyance, storage, handling, sale, or supply of goods to which this section applies, and inspect and search those premises;
- (b) require the production of, and inspect and make copies of, or take extracts from, any books or documents relating to the manufacture of or dealings in any goods to which this section applies that are kept or that he finds on those premises;
- (c) require the production of any goods to which this section applies that are kept or that he finds on those premises;
- (d) open and examine any receptacle, container, or package that is kept or that he finds on those premises and that he believes on reasonable grounds may contain goods to which this section applies;
- (e) examine any goods to which this section applies that are kept or that he finds on those premises;
- (f) seize and remove for analysis portions or samples of goods to which this section applies that are kept or that he finds on those premises; and
- (g) subject to subsection (3) of this section, seize any goods to which this section applies that are kept or that he finds on those premises.

(3) Without affecting the powers of an inspector under paragraph (f) of subsection (2) of this section, an inspector shall not seize any goods under paragraph (g) of that subsection—

- (a) unless the inspector believes on reasonable grounds that, in relation to the goods, a contravention of or a failure to comply with a provision of this Act is occurring or has occurred at any 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 the goods are for sale or are, without further manufacture other than packaging or labelling, intended for sale.

24—(1) An inspector shall, on the expiration of the prescribed period after the seizure of any goods under section twenty-three, Release of seized goods. N.S.W., s. 31. release those goods unless—

- (a) the forfeiture of the goods is consented to under section twenty-eight; or
 (b) a court of petty sessions orders under section twenty-five that the goods be forfeited.

(2) The inspector may release goods that have been seized under section twenty-three before the expiration of the prescribed period.

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

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

(5) A court of petty sessions may, in a particular case, extend the period referred to in subsection (1) of this section.

25—(1) A court of petty sessions may order that, on the expiration of a period specified in the order, any goods that have been seized under section twenty-three and that are specified in the order be forfeited to Her Majesty. Order that seized goods be forfeited. N.S.W., s. 32. Tas., s. 84.

(2) An order under this section does not have effect in respect of any goods that have been released under section twenty-four.

26—(1) A court of petty sessions may order that a person specified in the order pay to an inspector specified therein such amount of money as is specified therein, being— Order that expenses be paid. N.S.W., s. 33.

- (a) an amount of money that the court deems to be the reasonable expenses of seizing, forfeiting, and disposing of any goods under this Part and, where those goods were submitted by an inspector for analysis pursuant to Division II of this Part, the reasonable expenses of that analysis; or

(b) two hundred dollars,
whichever is the lesser amount.

(2) An order may be made under this section in respect of—

- (a) goods the forfeiture of which is or was consented to under section twenty-eight; or
- (b) goods that are specified in an order under section twenty-five.

(3) Section ninety-two A of the *Justices Act 1959* applies to and in relation to an order under this section as if the order were a summary conviction or order made under that Act for the payment of a sum of money for costs.

(4) An inspector to whom an amount is paid pursuant to an order under this section shall forthwith pay that amount, or cause that amount to be paid, into the Treasury to the credit of the Consolidated Revenue.

Storage of and
interference
with seized
goods.
N.S.W., s. 35.

27—(1) Subject to any direction that may be given by the Minister, goods that have been seized under this Part 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 Part.

(2) No person shall remove, alter, or interfere in any way with goods that have been seized under this Part without the authority of the Minister or of an inspector.

Forfeiture of
goods with
consent.
N.S.W., s. 36.

28 Where an inspector has seized any goods under section twenty-three, and the owner of the goods or the person in whose possession, care, custody, or control they were at the time of the seizure consents in writing to their forfeiture, the goods are thereupon forfeited to Her Majesty.

Disposal of
forfeited
goods.
N.S.W., s. 37.

29 Goods that are forfeited to Her Majesty under this Part may be disposed of in such manner as the Minister may direct, either generally or in a particular case or class of cases.

30—(1) No person shall—

(a) wilfully delay or obstruct an inspector in the exercise of any of the inspector's powers under this Act; or

(b) fail to produce any goods, books, or documents that that person is required to produce under this Act, unless those goods, books, or documents are not in his possession, care, custody, or control.

Obstruction of
inspector.
N.S.W., s. 38.
Tas., s. 82.

(2) If the admittance of an inspector to any premises into which he seeks to enter pursuant to section twenty-three is prevented or is delayed for such time that it may reasonably be inferred that wilful delay was intended, the occupier of the premises, and any other person who refuses or delays the admission of the inspector, is guilty of an offence against this Act.

Penalty: One thousand dollars.

(3) In proceedings in respect of an offence against this section in relation to the delaying or obstructing of an inspector, if it is shown that the entrance of an inspector into any premises was prevented or delayed by the existence of a barrier or obstruction in or on the premises, it shall be presumed, unless the contrary is proved, that the barrier or obstruction was intended to prevent or delay the entry of the inspector into the premises.

Division II—Analysis of goods.

31—(1) On payment or tender to a person (in this section referred to as "the seller") who is engaged in the business of selling or manufacturing therapeutic goods or cosmetics or to the agent or servant of the seller, or to a person in charge of therapeutic goods or cosmetics, either in transit or otherwise, of the current market value thereof or at the rate of payment prescribed, an inspector may demand and select and take or obtain a sample of the therapeutic goods or cosmetics as required by him for the purposes of this Act.

Power to
demand, select,
and take
samples.
Tas., s. 60.

(2) The inspector may require the seller, or his agent or servant, or the person in charge of the therapeutic goods or cosmetics, either in transit or otherwise, to show, and permit the inspection of, any package or container in which the therapeutic goods or cosmetics are kept, and may take or draw, or require the seller or his agent or servant, or the person so in charge of the substance, to take or draw, from the package or container the sample demanded.

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

(4) The procuring by an inspector of a sample of therapeutic goods or cosmetics pursuant to this section and the payment or tender of the current market value thereof or at the rate of payment prescribed shall, for the purposes of this Act, be deemed to be a sale by the seller, or by his agent or servant or the person in charge of the therapeutic goods or cosmetics, as the case may be, to the inspector of the therapeutic goods or cosmetics contained in the sample.

(5) If rates have been prescribed for the payment of samples of therapeutic goods or cosmetics, it is not necessary for an inspector to tender a higher price for a sample.

(6) A person may, on payment of the prescribed fee together with the cost of the sample, require an inspector to purchase a sample of any therapeutic goods or cosmetics and submit the sample for analysis.

Analysis of
goods procured
by an inspector.
N.S.W., s. 40.
Tas., s. 61.

32—(1) Where a sample is procured by an inspector, as provided by section thirty-one, for the purposes of analysis the inspector shall—

- (a) forthwith inform the person from whom he procured the sample of the purpose for which he procured the sample;
- (b) except as otherwise provided in this Act, forthwith divide the sample into three 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 vessel, container, or package, with some distinctive mark of identification;
- (d) deliver, or, if 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;
- (g) within twenty-eight days after procuring the sample, transmit a copy of the analyst's report of the analysis of his portion to any person against whom the inspector intends to take proceedings in respect of the sample analysed; and

(b) within a reasonable time after procuring the sample, transmit a copy of the analyst's report of the analysis of his portion—

- (i) to the seller, where the sample is procured from the seller or the agent or servant of the seller; or
- (ii) to the owner of the therapeutic goods or cosmetics, where the sample is procured from a person in charge thereof.

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

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

(4) Subject to subsection (5) of this section, in proceedings under this Act in respect of any therapeutic goods or cosmetics a sample of which has been submitted to an analyst as provided in this section, the court hearing the proceedings shall not receive the certificate of the analyst as evidence pursuant to section forty-eight unless it is satisfied that the provisions of this section have been complied with.

(5) In proceedings under this Act in respect of any therapeutic goods or cosmetics bought in the usual course of business by a person other than an inspector, if it is proved 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 the analyst thereon may be received as evidence without proof of compliance with the preceding provisions of this section.

33—(1) Where—

- (a) a person buys any therapeutic goods or cosmetics; or
- (b) an inspector procures or seizes a sample of any therapeutic goods or cosmetics,

Forwarding
of sample
by post.
Tas., s. 62

at a place outside a radius of twenty-five kilometres from the General Post Office at Hobart, the sample may be forwarded to an analyst by post or in any other convenient way, in which case the certificate of the analyst that, on receipt by him, the seal thereon was unbroken, is sufficient evidence of identity.

(2) A charge for postage or carriage shall be deemed to be one of the expenses of the analysis.

Right of owner or buyer to have goods analysed.
Tas., s. 63.

34 The owner or buyer of any therapeutic goods or cosmetics, on payment of a fee according to a scale to be prescribed, is entitled to have the goods or cosmetics analysed and to receive from the analyst a certificate of the result of his analysis.

Where method of analysis prescribed.
Tas., s. 64.

35 Where a method of analysis has been prescribed for the analysis of a particular kind of therapeutic goods or cosmetic, an analyst, either for the complainant or for the defendant in proceedings under this Act, shall, in his certificate of analysis, declare that he has followed the prescribed method in his analysis; but evidence is admissible on the part of the defence of an analysis made by a method other than the prescribed method to show that the prescribed method is not correct.

Costs of analysis.
Tas., s. 65.

36—(1) Where the prosecutor, in proceedings under this Act, has caused the therapeutic goods or cosmetics to which the proceedings relate to be analysed by an analyst, the court may, in case of a conviction, assess the reasonable expense of and attending the analysis and award it against the defendant as part of the costs of the prosecutor.

(2) In addition to the costs (if any) under subsection (1) of this section, the court may assess and award against the defendant—

- (a) as part of the costs of the prosecutor, the expenses incurred by the prosecutor while engaged in travelling to and attending the trial including the proportionate part of his salary while so engaged; and
- (b) where the Government Analyst or a member of his staff has given evidence at the trial, such costs in respect of his attendance as the court may determine.

Copy of result of analysis to be supplied on demand in certain cases.
Tas., s. 66.

37 Subject to subsection (6) of section thirty-one, a copy of the certificate showing the result of an analysis of any therapeutic goods or cosmetics made at the request of the owner or buyer of the therapeutic goods or cosmetics or of an inspector shall, on demand,

be supplied by the analyst to the person from whom the therapeutic goods or cosmetics were taken or obtained, and to the manufacturer or his agent in the State.

38 A copy of a certificate of an inspector under subsection (2) of section fourteen shall, on demand, be supplied by the inspector to the person whose stocks of therapeutic goods or cosmetics were inspected by the inspector or to that person's agent in the State.

Copy of inspector's certificate to be supplied on demand in certain cases. Tas., s. 67.

39 Where a copy of the certificate is supplied to any person by—

(a) an analyst in pursuance of section thirty-seven; or

(b) an inspector in pursuance of section thirty-eight,

the analyst or the inspector shall, on demand, supply to that person such number of additional copies of the certificate as he thinks fit.

Additional copies of certificate. Tas., s. 68.

40 No person shall, for trade purposes or advertisements, use an analysis made for the purposes of this Part.

Penalty: Twenty dollars.

Analysis not to be referred to for trade purposes. N.S.W., s. 40 (4). Tas., s. 69.

Division III—Legal proceedings and offences.

41 On a complaint under this Act concerning any therapeutic goods or cosmetics, the summons shall not be made returnable less than ten days after the day on which it is served.

Return day of summons. Tas., s. 70.

42 In proceedings under this Act concerning any therapeutic goods or cosmetics, there shall be served with the summons a copy of any analyst's certificate or inspector's certificate that may have been obtained on behalf of the complainant.

Copy of analyst's certificate. Tas., s. 71.

43 A witness on behalf of the prosecution in proceedings under this Act is not obliged to disclose—

(a) the fact that he received any information;

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

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

Source of information of witness or reports to inspector need not be disclosed. Tas., s. 72.

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

Reports to inspector need not be disclosed. Tas., s. 73.

Agent or servant liable in addition to principal.
Tas., s. 75.

45—(1) Subject to subsection (2) of this section, in proceedings under this Act for an offence in relation to any therapeutic goods or cosmetics, it is no defence that the defendant is only the agent or servant of the owner of, or person dealing in, those goods or that cosmetic but the agent or servant and the owner or person dealing in those goods or that cosmetic are both liable.

(2) A servant is not liable if he proves that the offence was committed in a store, shop, stall, or other similar place in which business was, at the time of the commission of the offence, conducted under the personal superintendence of the owner of the business or some manager or other person representing him.

Right of agent or servant to recover from principal.
Tas., s. 76.

46—(1) If the defendant in proceedings under this Act for an offence in relation to any therapeutic goods or cosmetics, being the agent or servant of the owner or person dealing in those goods or cosmetics, proves that he sold or supplied the goods or cosmetics without knowledge that a provision of this Act with respect to the goods or cosmetics or a container or package in which the goods or cosmetics were contained had been contravened or had not been complied with, he may, whether his principal or employer has or has not been convicted and fined, recover in a court of competent jurisdiction from his principal or employer the amount of any penalty imposed on the agent or servant in the proceedings, together with the costs paid or payable by him on his conviction and those paid or payable by him in and about his defence to the proceedings.

(2) Where an agent or servant has been convicted under this Act, the court before which he is convicted may suspend the operation of the conviction for a period not exceeding three months, to enable the agent or servant to recover from his principal or employer as provided in subsection (1) of this section.

Defence available to defendant where some other person is responsible for commission of offence.
Tas., s. 77.

47—(1) A person (in this section referred to as “the original defendant”) against whom proceedings are brought in respect of an offence against this Act is entitled to have any person (in this section referred to as “the third party”) to whose act or default the original defendant alleges that the commission of the offence was due brought before the court in those proceedings and if, after the offence is proved, the original defendant proves that the commission of the offence was due to the act or default of the third party, the third party may be convicted of the offence, and, if the original defendant further proves that he used all due diligence to secure the

compliance with the provisions of this Act in respect of the contravention in relation to which the proceedings are brought, he shall be acquitted of the offence.

(2) To avail himself of the provisions of subsection (1) of this section the original defendant may, on three clear days' notice to the prosecutor, apply to a justice for a summons to the third party and—

(a) the justice shall make the return day of that summons conform to the principle of section forty-one and amend the return day of the summons on the complaint accordingly; and

(b) the justice's summons to the third party shall recite the complaint and the original defendant's allegation on which it is issued.

(3) Where the original defendant avails himself of the provisions of subsection (1) of this section—

(a) the prosecutor and the third party are entitled to cross-examine the original defendant, if he gives evidence, and to cross-examine any witness called by him in support of his evidence, and to call rebutting evidence; and

(b) the court before which the proceedings are brought may make such order as the court thinks fit for the payment of costs by any party to the proceedings to any other party thereto.

(4) Where it appears to an inspector that an offence under this Act has been committed in respect of which proceedings might be taken against some person and the inspector is reasonably satisfied that the offence was due to an act or default of some other person and that the first-mentioned person could have that other person brought before a court in accordance with subsection (1) of this section, the inspector may cause proceedings to be brought against that other person without first causing proceedings to be brought against the first-mentioned person, and in any proceedings so brought that other person may be charged with and, on proof that the commission of the offence was due to his act or default, may be convicted of the offence with which the first-mentioned person might have been charged.

48—(1) In proceedings in respect of an offence against this Act a certificate purporting to be signed by the Minister and to certify that—

Evidentiary
provisions.
N.S.W., s. 53.

(a) a person specified therein was or was not the holder of a licence under this Act;
 (b) a person specified therein was an analyst; or
 (c) a person specified therein was an inspector,
 on any day, or during any period, specified therein, is admissible in evidence and is evidence of the fact so certified.

(2) In any such proceedings, a certificate purporting to be signed by an inspector and to certify that any matter specified therein is a copy of, or extract from, a book or document made or taken by him under this Act is admissible in evidence without production of the book or document.

(3) In any such proceedings, a certificate purporting to be signed by an analyst and setting out the results of an analysis of any therapeutic goods or cosmetics under section thirty-two 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 as may be specified therein.

Offences and
penalty.
N.S.W., ss.
48, 49,
Tas., s. 85.

49—(1) A person who contravenes or fails to comply with a provision of this Act that is applicable to him is guilty of an offence against this Act.

(2) A person who is guilty of an offence against this Act for which no other penalty is expressly prescribed elsewhere in this Act is liable to a fine of eight hundred dollars or imprisonment for six months, or to both.

Offences by
bodies
corporate.
N.S.W., s. 55.
Tas., s. 86.

50 Where a body corporate is convicted of an offence against this Act, each director or member of the governing authority of the body corporate and each officer concerned in the management of the body corporate is guilty of the like offence unless he proves that he used all due diligence to prevent the commission of the offence or that the offence was committed without his knowledge or consent or contrary to his orders or directions.

Appeals.
N.S.W., s. 52.

51—(1) A person who is aggrieved by—

- (a) the refusal of the Minister to grant a licence under section seven;
- (b) the revocation or suspension of such a licence;
- (c) the making of—
 - (i) an order under section twenty-two; or
 - (ii) a report or recommendation under section fifty-seven, section fifty-eight, or section fifty-nine;
 or

(d) the refusal of the Minister to grant a permit under section fifty-five, or the terms of a permit granted under that section, or the cancellation of such a permit, may appeal therefrom to a judge, who may hear and determine the appeal.

(2) On the hearing of an appeal against the making of a report or recommendation to which sub-paragraph (ii) of paragraph (c) of subsection (1) of this section relates, the judge may vary the report or recommendation or rescind it and make a fresh report or recommendation.

(3) On an appeal under paragraph (d) of subsection (1) of this section the judge may direct the Minister to issue a permit in the terms determined by the judge, and the Minister shall comply with the direction.

(4) A judge in chambers may order that a report shall not be published, or that a recommendation shall not be acted on, pending an appeal against it.

(5) A judge may hear an appeal under this section in open court or in chambers and may make such order as to costs as to him seems proper.

(6) The Governor may make regulations prescribing the cases in which, and the persons to whom, notice shall be given of a report or recommendation referred to in this section, and generally regulating appeals under this section.

PART VI.

MISCELLANEOUS.

Division I—General.

52 The provisions of—

- (a) section forty-seven of the *Acts Interpretation Act 1931*; and
 (b) the *Subordinate Legislation Committee Act 1969*,

Application of certain Acts to orders under this Act.

apply to and in relation to an order made by the Minister under section fifteen or section sixteen as if the order were a regulation.

53—(1) The Minister may, by notice in writing served on a person who manufactures in, or imports into, the State, or sells or supplies any therapeutic goods or cosmetics, require that person to furnish, in writing, to the Minister or to such other person as may be specified in the notice, within such time (not being less than fourteen days) as may be so specified, such information relating to those goods or cosmetics as may be referred to in the notice.

Power of Minister to require certain information.
 N.S.W., s. 41.

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

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

(4) A person on whom a notice under subsection (1) of this section is served shall not, in purported compliance with the notice, knowingly furnish any information that is false or misleading in a material particular.

Selling
therapeutic
goods by means
of automatic
machines
prohibited.
N.S.W., s. 42.
Tas., s. 80.

54 No person shall—

- (a) whether on or about his premises or elsewhere—
- (i) install an automatic machine for the sale or supply of any therapeutic goods; or
 - (ii) sell or supply any such goods by means of an automatic machine;
- (b) permit or suffer an automatic machine designed for, or capable of being used for, the sale of any therapeutic goods to be installed on his premises or on premises under his control;
- (c) place any therapeutic goods or permit or suffer any therapeutic goods to be placed in an automatic 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 any therapeutic goods by means of an automatic machine on the premises of, or under the control of, the first-mentioned person.

Penalty: Two hundred dollars or imprisonment for six months, together with a daily penalty of twenty dollars in the case of a continuing offence.

Hawking, &c.,
of therapeutic
goods.

55—(1) Except in accordance with a written permit issued by the Minister for the purposes of this section, no person shall—

- (a) sell or supply therapeutic goods, or distribute therapeutic goods free or as samples, in a street or from place to place;
- (b) hawk or peddle therapeutic goods; or
- (c) whether by appointment or otherwise, go from place to place selling, supplying, or distributing therapeutic goods (whether free or as samples).

(2) The Minister may issue permits for the purposes of this section and may, in such manner as may be prescribed, cancel a permit so issued; and any such permit may specify the person by whom the authority granted by the permit may be exercised, and the conditions, limitations, or restrictions subject to which that authority may be exercised.

(3) Subsection (1) of this section does not apply to or in relation to the free distribution of clinical samples of therapeutic goods other than narcotic substances (within the meaning of the *Poisons Act* 1971) to medical practitioners, dentists, or veterinary surgeons by persons engaged in the manufacture of, or dealing in, any such goods, where the distribution is made to the medical practitioner, dentist, or veterinary surgeon personally or by posting, by registered post, a letter or parcel containing the goods addressed to him.

56 The regulations may prohibit or regulate the sale or supply of a therapeutic appliance that is of a class of therapeutic appliances specified or described in the regulations.

Prohibition of sale or supply of certain therapeutic appliances.

57—(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 the goods or cosmetics, and shall cause the results of the examination to be compared with any advertisement that relates to the goods or cosmetics and the price at which the goods or cosmetics are sold.

Examination and report on therapeutic goods that have been advertised.

(2) The person carrying out an examination and comparison under subsection (1) of this section shall prepare and forward to the Minister a report on the whole matter, which may include any comment which that person thinks desirable in the public interest.

(3) Upon receipt of a report under this section, the Minister may thereupon cause the report to be published in the *Gazette* and in a newspaper or public print that circulates within the State, and to be distributed among the public in any other way, and no action lies in respect of the publication.

(4) The proprietor or manager of a newspaper or public print may republish therein a report that has been published under subsection (3) of this section, and no action lies in respect of the republication.

58—(1) The Governor, on the recommendation of the Minister, or of a judge on appeal from the Minister, may by notification in the *Gazette* and in a newspaper that circulates in the State, prohibit, after the date therein mentioned, the advertising, sale, or supply

Prohibition of sale of injurious, &c., therapeutic goods.
N.S.W., s. 28.
No. 75 of 1962 (Tas.), s. 72.

of any therapeutic goods that, in the opinion of the Minister or of the judge, are injurious to life or health, or that by reason of their inactivity or inefficiency are useless for the advertised purposes of cure.

(2) No person shall—

- (a) advertise, sell, or supply any therapeutic goods in contravention of an order under this section;
- (b) being the proprietor or manager of a newspaper or other public print, publish any advertisement that is prohibited by such an order; or
- (c) print or distribute any advertisement that is so prohibited.

Prohibition of sale of certain substances.

No. 75 of 1962 (Tas.), s. 73.

59—(1) The Governor, on the recommendation of the Minister, or of a judge on appeal from the Minister, by notification in the *Gazette*, may prohibit the sale of a substance or compound as a disinfectant, germicide, antiseptic, or preservative.

(2) No person shall sell a substance or compound the sale of which is prohibited under this section.

Labelling of certain substances.

No. 75 of 1962 (Tas.), s. 74.

60—(1) The Minister, by notification in the *Gazette*, may 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 or directions as he deems fit shall be set out on a statement or label written on or attached to any container or package containing that substance or compound.

(2) No person shall sell a substance or compound in contravention of a notification under this section.

Service of notices, &c.
N.S.W., s. 45.

61 A notice under this Act, or an order under section twenty-two, may be served on a person—

- (a) by delivering it personally to that person;
- (b) by delivering it to the place last-known to the Minister as that person's place of abode or business and by leaving it there with some person for that person; or
- (c) by posting it in an envelope duly stamped and addressed to that person at the place last-known to the Minister as that person's place of abode or business.

Protection from liability.
No. 81 of 1971 (Tas.), s. 91.

62 No act, matter, or thing done or omitted to be done in good faith by the Minister, or by an inspector, or by a person to whom any of the Minister's functions have been delegated, in the administration or intended administration of this Act, or in the exercise or performance or intended exercise or performance of any of the functions of the Minister, or of the Director-General or of such a

person under this Act, subjects the Minister, inspector, or such a person to any liability (whether civil or criminal) in respect of that act, matter, or thing.

Division II—Regulations and orders.

63—(1) The Governor may make regulations for the purposes of this Act and, in particular and without prejudice to the generality of the provisions of this subsection, may make regulations for or with respect to—

Regulations.
N.S.W., s. 46.

- (a) 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 any class thereof and defining the expressions “general standard” and “specific standard” respectively;
- (b) 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 any class thereof;
- (c) the prohibition of the addition to or admixture with therapeutic goods or cosmetics or any class thereof of specified substances or classes of substances;
- (d) the packing and labelling of therapeutic goods or cosmetics or of any class thereof and of containers and packages containing therapeutic goods or cosmetics or any class thereof;
- (e) 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 any such containers and packages;
- (f) the regulation, control, and restriction of the contents of any such labels and of advertisements relating to therapeutic goods, and the prohibition of the use in any 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 any particular use;
- (g) requiring the inclusion in any such labels or advertisements of such information as may be specified in the regulations and prohibiting the omission, in prescribed cases, from

- any such labels or advertisements of prescribed kinds of statements or information;
- (b) 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;
 - (i) 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 any class thereof 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;
 - (j) requiring the giving of notice to a prescribed person in respect of any therapeutic goods or cosmetics that the manufacturer of the goods or the distributor in the State of the goods 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 such a notice;
 - (k) the testing and analysis of therapeutic goods or cosmetics;
 - (l) the exemption of persons, goods, containers, and packages in prescribed cases from all or any of the provisions of the regulations;
 - (m) the delivery up of licences granted under this Act and the issue of substitute or duplicate licences;
 - (n) the records that shall be kept by persons engaged in the manufacture, distribution, conveyance, storage, handling, sale, or supply of therapeutic goods or cosmetics;
 - (o) the procedure to be observed by inspectors when seizing and removing portions or samples of therapeutic goods or cosmetics pursuant to section twenty-three;
 - (p) the determination of the requirements to which therapeutic goods or cosmetics or any class thereof are to conform when sold; and
 - (q) the fees to be paid in relation to the issue of licences under section seven.
- (2) A standard in relation to any therapeutic goods or cosmetics may relate to—
- (a) the composition, strength, potency, stability, purity, quality, construction, or other properties thereof;

- (b) the quantity thereof;
- (c) the manner in which they were manufactured;
- (d) the packaging and labelling thereof; or
- (e) the manner in which they have been stored, handled, or conveyed.

(3) A standard in relation to any therapeutic goods or cosmetics may—

- (a) prohibit the goods from—
 - (i) containing a prescribed substance; or
 - (ii) containing 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 in relation to any 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 shall be 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) Where therapeutic goods or cosmetics are sold after the expiry date that is, in accordance with a standard referred to in subsection (4) of this section, stated in relation to the goods, the goods shall, except in such circumstances as may be prescribed, be deemed not to conform to that standard.

(7) Where, in accordance with a standard in relation to any therapeutic goods or cosmetics, any prescribed information or statement appears on a label, container, or package, the therapeutic goods or cosmetics shall be deemed not to conform to that standard if there is included thereon any comment, reference, or explanation that expressly or impliedly contradicts, qualifies, or modifies that information or statement.

(8) The regulations may adopt, either specifically or by reference and either with or without modifications—

- (a) any standards determined under, or prescribed or set out in—

- (i) the Commonwealth Act or any regulation or order thereunder; or
 - (ii) the *British Pharmacopoeia*, the *British Pharmaceutical Codex*, the *British Veterinary Codex*, or any other prescribed publication; and
- (b) any method of testing or analysis prescribed under the Commonwealth Act or set out or described in any publication referred to or prescribed under sub-paragraph (ii) of paragraph (a) of this subsection.
- (9) The regulations may—
- (a) 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;
 - (b) be made so as to apply to or in relation to therapeutic goods or cosmetics generally or specified classes of therapeutic goods or cosmetics;
 - (c) make different provision in relation to different classes of therapeutic goods or cosmetics or differ according to differences in the purposes for which therapeutic goods or cosmetics are sold, supplied, or used;
 - (d) prescribe different fees in relation to the issue of different kinds of licences under section seven; and
 - (e) impose penalties, not exceeding four hundred dollars, for offences against the regulations.
- (10) The regulations may, in making provision for or with respect to the determination of a standard, adopt by reference the whole or any part of a monograph or other material contained in a prescribed publication or in any such monograph of other material as modified pursuant to subsection (11) of this section.
- (11) The regulations may provide for the modification of any monograph or other material adopted under subsection (10) of this section.

Provisions
applicable to
regulations
and orders.
N.S.W., s. 47.

64—(1) Regulations and orders under this Act may be made so as to differ according to time, place, and circumstances.

(2) A regulation or an order under this Act may authorize any matter or thing to be from time to time determined, applied, or regulated by a person or body specified therein.

(3) Where by regulations or orders under this Act a power is conferred on any person or body to make a determination or to exercise any other discretion those regulations or orders may make

provision for the granting of a right of appeal to a judge in respect of the determination or the exercise of the discretion, and may make provision with respect to the bringing and the hearing and determination of the appeal.

(4) Therapeutic goods or cosmetics may be specified or described in a regulation or order under this Act by reference to any act, matter, or thing specified or described in the regulation or order, and, without affecting the generality of the foregoing provisions of this subsection, may be specified or described by reference to any one or more of the following:—

- (a) The common or scientific name of the goods or cosmetics;
- (b) Any class of goods or cosmetics;
- (c) The composition of the goods or cosmetics;
- (d) The use or intended use of the goods or cosmetics;
- (e) The purpose for which the goods or cosmetics may be used;
- (f) Any dealing or proposed dealing in or in respect of the goods or cosmetics; or
- (g) The manner in which the goods or cosmetics are packed.

(5) A regulation or an order under this Act may be made so as to apply to or in relation to—

- (a) any act, matter, or thing, or all acts, matters, or things, or any class of acts, matters, or things, specified or described in the regulation or order; or
- (b) all acts, matters, or things or any class of acts, matters, or things so specified or described other than—
 - (i) any act, matter, or thing so specified or described that is expressed to be excluded; or
 - (ii) any class of acts, matters, or things so specified or described that is expressed to be excluded.

(6) Where a provision of this Act authorizes any act, matter, or thing to be prescribed or to be specified or described in any regulation or order under this Act, the provisions of subsection (4) of this section apply, without affecting the generality of that subsection, to a regulation or order prescribing, or specifying, or describing that act, matter, or thing.

