

## THERAPEUTIC SUBSTANCES.

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**No. 72 of 1953.**

An Act to provide standards for certain  
Therapeutic Substances, and for other purposes.

[Assented to 5th December, 1953.]

**B**E it enacted by the Queen's Most Excellent Majesty, the Senate,  
and the House of Representatives of the Commonwealth of  
Australia, as follows :—

Short title.

1. This Act may be cited as the *Therapeutic Substances Act 1953*.

2. This Act shall come into operation on a date to be fixed by Proclamation. Commencement.

3. The *Therapeutic Substances Act 1937* and the *Therapeutic Substances Act 1938* are repealed. Repeal.

4.—(1.) In this Act, unless the contrary intention appears— Interpretation.

“controlled therapeutic substance” means a therapeutic substance—

(a) which is the subject of a monograph in the British Pharmacopoeia or in the British Pharmaceutical Codex and is not specified in the regulations as a therapeutic substance which is not a controlled therapeutic substance ; or

(b) which is specified in the regulations as a controlled therapeutic substance ;

“official name”, in relation to a controlled therapeutic substance, means a name or title, or an abbreviation or synonym of a name or title, given or specified as a name or title, or as an abbreviation or synonym of a name or title, of the therapeutic substance in a monograph in the British Pharmacopoeia or the British Pharmaceutical Codex or in the regulations ;

“pharmaceutical benefit” means a drug, medicinal preparation or medicinal compound which is a pharmaceutical benefit for the purposes of a law of the Commonwealth relating to the provision of pharmaceutical benefits ;

“substance” includes a mixture or compound of substances ;

“the British Pharmaceutical Codex” means—

(a) the latest edition for the time being of the book called the British Pharmaceutical Codex published by direction of the Council of the Pharmaceutical Society of Great Britain ; or

(b) if that edition has been added to or amended—that edition as affected by the additions or amendments ;

“the British Pharmacopoeia” means—

(a) the latest edition (being an edition that has taken effect) for the time being of the book called the British Pharmacopoeia published under the direction of the General Medical Council of the United Kingdom ; or

(b) if that edition has been added to or amended by additions or amendments that have taken effect—that edition as affected by those additions or amendments ;

“therapeutic substance” means a substance which has a therapeutic use and includes a surgical ligature, suture or dressing, but does not include a vaccine prepared from microscopic organisms from the body of a person or animal for use in the treatment of that person or animal only ;

“ therapeutic use ” means a use for the purpose of—

- (a) preventing, diagnosing, curing or alleviating of a disease, ailment, defect or injury in persons or animals ;
- (b) influencing, inhibiting or modifying of a physiological process in persons or animals ; or
- (c) testing of susceptibility to a disease or ailment in persons or animals ;

“ the standard ” means—

- (a) in relation to a therapeutic substance which is specified in the regulations as a controlled therapeutic substance—the standard constituted by the description of that substance in the regulations ;
- (b) in relation to a therapeutic substance to which the last preceding paragraph does not apply but which is the subject of a monograph in the British Pharmacopoeia—the standard constituted by the statements in that monograph ; and
- (c) in relation to a therapeutic substance to which neither of the last two preceding paragraphs applies but which is the subject of a monograph in the British Pharmaceutical Codex—the standard constituted by the statements in that monograph.

(2.) For the purposes of this Act, goods shall be deemed to be represented to consist of a controlled therapeutic substance—

(a) if the goods bear a name or description—

- (i) which is, or is likely to be taken for, an official name of that controlled therapeutic substance ; or
- (ii) which is likely to cause the goods to be taken to consist of that controlled therapeutic substance ;

or

(b) if the goods are otherwise represented, by writing or otherwise, to consist of that controlled therapeutic substance.

(3.) For the purposes of this Act, goods shall be deemed to bear a name, description or other particulars if that name or description or those particulars are set out on, or on a label affixed or attached to, the goods or a container or package containing the goods.

Regulations  
may modify  
monographs.

5. The regulations may provide that a monograph in the British Pharmacopoeia or the British Pharmaceutical Codex shall, for the purposes of this Act, be deemed to be modified in accordance with the regulations.

Regulations  
may provide for  
packaging and  
labelling.

6. The regulations may provide that, for the purposes of a provision of this Act, any goods that consist of a controlled therapeutic substance shall be packed and labelled as provided in the regulations and, for the purposes of that provision, goods consisting of that therapeutic substance that are not packed and labelled as so provided shall be deemed not to conform to the standard for that therapeutic substance.

7.—(1.) The importation into Australia is prohibited of—

(a) goods that consist of a therapeutic substance but do not bear—

(i) a name or description that is an accepted scientific or technical name or description of the substance, or a name or description that indicates the composition of the substance ; and

(ii) particulars of the name and address of the manufacturer of the goods ;

(b) goods that consist of a controlled therapeutic substance but do not bear a name that is an official name of that controlled therapeutic substance and, if the controlled therapeutic substance has an official name in the English language, is in that language ; and

(c) goods that consist of, or are represented to consist of, a controlled therapeutic substance but do not conform to the standard for that controlled therapeutic substance or do not bear—

(i) particulars of the quantity, by volume or weight, of the goods ; and

(ii) such other particulars as are prescribed.

(2.) Goods the importation of which is prohibited under the last preceding sub-section are prohibited imports for the purposes of the *Customs Act 1901-1953*, and the provisions of that Act relating to prohibited imports apply accordingly.

8.—(1.) Where the Minister is satisfied that a person is engaged in scientific research, he may, by instrument in writing and subject to such conditions, if any, as are specified in the instrument, exempt from the last preceding section the importation of goods by that person for the purposes of scientific research.

(2.) Where the Minister is satisfied that, in the public interest, it is proper for him so to do, he may, by instrument in writing and subject to such conditions, if any, as are specified in the instrument, exempt from the last preceding section the importation of goods specified in the instrument by a person specified in the instrument.

(3.) Where a condition specified in an instrument of exemption issued under this section is not complied with, the person in whose favour the exemption was granted shall be deemed to have committed an offence against this Act.

9.—(1.) A person shall not, without the consent in writing of the Minister, cause, suffer or permit goods that consist of a therapeutic substance to become the subject of trade or commerce among the States unless—

(a) the goods bear—

(i) a name or description that is an accepted scientific or technical name or description of the substance, or a name or description that indicates the composition of the substance ; and

(ii) particulars of the name and address of the manufacturer of the goods ;

Importation of  
therapeutic  
substances.

Exemptions  
where  
importation is  
for scientific  
purposes or in  
public interest.

Interstate  
trade.

- (b) in the case of goods that consist of a controlled therapeutic substance, they bear a name that is an official name of that controlled therapeutic substance and, if the controlled therapeutic substance has an official name in the English language, is in that language ; and
- (c) in the case of goods that consist of, or are represented to consist of, a controlled therapeutic substance, they conform to the standard for that controlled therapeutic substance and bear—
- (i) particulars of the quantity, by volume or weight, of the goods ; and
  - (ii) such other particulars as are prescribed.

(2.) The consent of the Minister under the last preceding subsection may be given either unconditionally or subject to conditions.

(3.) Where a condition subject to which a consent is given under this section is not complied with, the person to whom the consent was given shall be deemed to have committed an offence against this Act.

Standards of  
pharmaceutical  
benefits.

**10.**—(1.) Where a pharmaceutical benefit is a controlled therapeutic substance, a person shall not supply goods as that pharmaceutical benefit under a law of the Commonwealth relating to the provision of pharmaceutical benefits unless the goods conform to the standard for that controlled therapeutic substance.

(2.) Where an ingredient in a pharmaceutical benefit is a controlled therapeutic substance, a person shall not supply goods as that pharmaceutical benefit under a law of the Commonwealth relating to the provision of pharmaceutical benefits if, in the preparation of those goods, there has been used, in lieu of that ingredient, a substance which does not conform to the standard for that controlled therapeutic substance.

(3.) Where a person supplies goods as a pharmaceutical benefit under a law of the Commonwealth relating to the provision of pharmaceutical benefits in contravention of this section, that supply shall, for the purposes of that law, be deemed not to be a supply of a pharmaceutical benefit in accordance with that law.

Therapeutic  
substances  
supplied to the  
Commonwealth.

**11.** A person shall not supply to the Commonwealth or to an authority of the Commonwealth or of a Territory of the Commonwealth goods which consist of, or are represented to consist of, a controlled therapeutic substance unless the goods conform to the standard for that controlled therapeutic substance.

Exemptions  
in respect of  
goods not to  
be used for  
therapeutic  
purposes.

**12.**—(1.) Where the Minister, or a person authorized by the Minister to grant exemptions under this section, is satisfied that goods are not intended for a therapeutic use, he may, by instrument in writing and subject to such conditions, if any, as are specified in the instrument—

- (a) exempt from section seven of this Act the importation of those goods by a person specified in the instrument ; or

(b) exempt a person specified in the instrument from compliance with section nine or eleven of this Act in respect of those goods.

(2.) Where a condition specified in an instrument of exemption issued under this section is not complied with, the person in whose favour the exemption was granted shall be deemed to have committed an offence against this Act.

13.—(1.) The regulations may make provision for or in relation to the examination, testing and analysing of goods to which this section applies.

Regulations may provide for the examination, testing and analysing of therapeutic substances.

(2.) Without limiting the generality of the last preceding subsection, the regulations which may be made by virtue of that subsection include regulations making provision—

- (a) for or in relation to the taking of samples of goods to which this section applies ;
- (b) for or in relation to the authorization of persons to take, and to enter upon premises for the purposes of taking, samples of goods to which this section applies and to make examinations and inquiries with respect to matters relating to goods to which this section applies ;
- (c) for prescribing tests for the purpose of ascertaining whether goods conform to a standard ;
- (d) for or in relation to the appointment or establishment of laboratories for the examination, testing and analysing of goods to which this section applies ;
- (e) for the issue of certificates by persons who have examined, tested or analysed goods to which this section applies ; and
- (f) for prescribing the extent to which certificates issued under the regulations are evidence of matters stated in the certificates.

(3.) The goods to which this section applies are goods that consist of a therapeutic substance, being goods—

- (a) which are imported into Australia ;
- (b) which are proposed to be exported from Australia ;
- (c) which have been, are or are proposed to be, the subject of trade or commerce among the States ;
- (d) which have been supplied as a pharmaceutical benefit under a law of the Commonwealth relating to the provision of pharmaceutical benefits or are in the possession of a person who is an approved pharmaceutical chemist under such a law at premises in respect of which he is so approved ; or
- (e) which have been supplied to the Commonwealth or to an authority of the Commonwealth or of a Territory of the Commonwealth or are in the possession of a person who is a party to a subsisting contract for the supply of therapeutic substances to the Commonwealth or to such an authority.

Punishment  
of offences.

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

(2.) An offence against this Act may be prosecuted either summarily or upon indictment, but an offender is not liable to be punished more than once in respect of the same offence.

(3.) The punishment for an offence against this Act is—

(a) if the offence is prosecuted summarily—a fine not exceeding One hundred pounds or imprisonment for a term not exceeding six months; or

(b) if the offence is prosecuted upon indictment—a fine not exceeding Five hundred pounds or imprisonment for a term not exceeding one year.

(4.) In addition to any other punishment, a court may, if it thinks fit, order the forfeiture of goods in respect of which an offence against this Act has been committed.

Courts to take  
judicial notice  
of British  
Pharmacopoeia  
and British  
Pharmaceutical  
Codex.

15. All courts shall, for the purposes of proceedings arising under this Act, take judicial notice of the British Pharmacopoeia and the British Pharmaceutical Codex.

Delegation.

16.—(1.) The Minister may, in relation to a particular matter or class of matters, or to a part of the Commonwealth, by writing under his hand, delegate to a person all or any of his powers under this Act except this power of delegation, so that the delegated powers may be exercised by the delegate with respect to the matter or class of matters, or the part of the Commonwealth, specified in the instrument of delegation.

(2.) A delegation under this section is revocable at will and does not prevent the exercise of a power by the Minister.

Act and  
regulations not  
in derogation of  
other  
Commonwealth  
laws.

17. The provisions of this Act and the regulations are in addition to, and do not derogate from the operation of, any other law of the Commonwealth.

Emergency  
quarantine  
measures.

18.—(1.) Where the Governor-General is satisfied that a therapeutic substance, or the use of a therapeutic substance—

(a) is causing, or is likely to cause, the occurrence in Australia of a serious outbreak of disease in persons or animals; or

(b) is endangering, or is likely to endanger, the life or health of persons or animals in Australia.

the Governor-General may, by Proclamation, declare that quarantine measures are necessary in relation to that therapeutic substance.

(2.) Where a Proclamation is in force under the last preceding sub-section in relation to a therapeutic substance, the Minister may, by order in writing, direct the person or persons to whom the order applies—

(a) to destroy, or to refrain from selling or distributing, any of that therapeutic substance which is in his or their possession; or

(b) not to prepare that therapeutic substance.

(3.) An order may be expressed to apply to persons generally, to persons included in a class of persons specified in the order or to a person specified in the order.

(4.) An order does not take effect—

(a) in the case of an order expressed to apply to a person specified in the order—until the order has been served on that person either personally or by sending it by post to, or by leaving it at, his last-known address ; and

(b) in any other case—until a copy of the order has been published in the *Gazette*.

(5.) A person to whom an order applies shall comply with the directions in that order.

**19.** The Governor-General may make regulations, not inconsistent with this Act, prescribing all matters which by this Act are required or permitted to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to this Act, and in particular—

**Regulations.**

(a) for describing, by reference to composition, strength, potency, stability, sterility, quantity, quality or method of preparation, a therapeutic substance that is specified in the regulations to be a controlled therapeutic substance ;

(b) for making provision for or in relation to—

(i) the establishment of committees to advise the Minister on matters relating to the importation into Australia of therapeutic substances and on such other matters as are prescribed, and the functions and powers of those committees ; and

(ii) the payment of remuneration and allowances to members of committees established under the regulations ; and

(c) for prescribing penalties not exceeding a fine of One hundred pounds or imprisonment for six months for offences against the regulations.

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