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Therapeutic Goods Bill 1989

Date Introduced: 5 October 1989
House: House of Representatives
Portfolio: Community Services and Health

Digest of Bill

Purpose

To establish standards and provide an assessment and licensing system to regulate the import, export, supply and manufacturing of certain therapeutic goods.

Background

Therapeutic goods include drugs, biological products such as vaccines, hormones, blood products and therapeutic devices. Therapeutic devices include any material, instrument, apparatus, machine, implement, implant etc., used in health care. It is estimated that in the Australian market there are over 14 000 therapeutic drug products and 25 000 therapeutic devices.¹

Most drugs marketed in Australia are either imported or manufactured locally from imported ingredients and are thus subject to Commonwealth import controls. The Customs (Prohibited Imports) Regulations regulate the importation of such drugs. Basically, the importation of drugs into Australia is prohibited unless the importer holds a permission or a licence issued by the Department of Community Services and Health (the Department). Licensed importers also require permission to distribute certain drugs. Under the Customs (Prohibited Imports) Regulations, the onus is placed on the manufacturer to undertake a recall where a licence to import a drug has been revoked. Mandatory recall powers are available through the *Trades Practices Act 1974*.

The *Therapeutic Goods Act 1966* sets standards for therapeutic goods that are imported, subject to interstate trade, are listed as benefit items under the Pharmaceutical Benefits Scheme or supplied to Commonwealth agencies. The standards relate to the composition, strength, potency, stability, sterility, quantity, quality, method of preparation, labelling and packaging of therapeutic goods. Under the Act the Minister can determine general standards and tests for particular dosage forms and direct that therapeutic goods be labelled in a particular way, or be supplied in containers which comply with specific requirements. The Therapeutics Division of the Department is concerned with the implementation of the standards. This includes testing of therapeutic goods to ensure that the standards are being observed. The Act also provides a Register of Therapeutic Goods. The Register provides a comprehensive record of information on all therapeutic drugs and devices available in Australia. The Register currently holds approximately 10 000 entries.²

Over the past ten years a number of reviews of the pharmaceutical industry and therapeutic goods program have been undertaken. The most recent of these was a report, in December 1988, by the Joint Committee of Public Accounts, titled *Therapeutic Goods – A Review of the Therapeutic Goods Evaluation and Testing Program*. The Committee's recommendations included that a Bill be introduced in the Autumn sitting of 1989 to provide uniform national legislation for the registration of therapeutic goods, licensing and inspection of manufacturers and wholesalers, application of standards and testing procedures; that a system of fees be introduced for the licensing of manufacturers, evaluation of therapeutic goods and entering of a good on the National Register of Therapeutic Goods; and that the Department commence monitoring advertisements to assess whether they comply with the guidelines.

Main Provisions

The Bill will have effect from 1 March 1990 (clause 2).

'Therapeutic goods' is defined as goods that are represented in any way to be, or likely to be taken to be, for therapeutic use (this includes goods used to cur, treat or diagnose an ailment or to effect a physiological process). The definition also includes goods for use as an ingredient or component in the manufacture of therapeutic goods, or for use as a container or part of a container for therapeutic goods (clause 3).

The object of the Bill will be to provide, within constitutional limitations, a national system of controls over therapeutic goods used in, or exported from, Australia (clause 4).

Clause 6 deals with the operation of the Bill. This is defined by reference to the Commonwealth's constitutional powers, particularly the corporations and interstate trade and commerce powers. This aims to satisfy the constitutional limits of the Commonwealth's power in this area.

Clause 7 will allow the Secretary of the Department (the Secretary) to declare, that particular goods are or are not therapeutic goods.

Clause 8 will allow the Secretary to require an importer or supplier of therapeutic goods, or goods being considered to be declared as therapeutic goods, to provide certain information about the goods, including composition, indications, directions for use or labelling, and advertising material. It will be an offence for a person, without reasonable excuse, to not provide information, or knowingly provide information that is false or misleading. The maximum penalty for breach of this provision will be a fine of \$6000.

Part 2 of the Bill (clauses 10 – 15) deals with the setting of standards for therapeutic goods and compliance with those standards. Clause 10 provides that the Minister may, by *Gazetta* of an order, establish a standard for therapeutic goods identified in the order. An order establishing a standard may deal with a number of matters, including the quality of the goods; procedures to be carried out in the manufacture of the goods; require that a matter be decided in accordance with a particular test; or require that the goods be labelled, or packaged in a particular way. The Minister is not to establish, revoke, or amend a standard without having consulted with a committee established by regulation to advise the Minister on standards. Orders establishing, revoking

or varying standards will be subject to disallowance by Parliament (clause 12). Clause 14 provides that it will be an offence, except with the consent of the Secretary, for a person to import, export, or supply within Australia therapeutic goods that do not conform with the standard applicable to them. The maximum penalty for breach of this provision will be a fine of \$24 000. No offence will have been committed where imported therapeutic goods do not comply with a standard because of the way they are labelled or packaged. The Secretary may place conditions on a consent issued under clause 14. It will be an offence for a person to breach a condition of a consent. The maximum penalty for breach of this provision will be a fine of \$12 000 (clause 15).

Part 3 of the Bill (clauses 16 – 33) deals with the establishment of the Australian Register of Therapeutic Goods (the Register) and the registration or listing of therapeutic goods. Clause 17 provides that the Secretary is to establish the Register for the purpose of compiling information and providing assessment of therapeutic goods used for humans. The Register is to comprise two parts, one for registered goods, and the other for listed goods. The regulations may prescribe the therapeutic goods required to be registered or listed and the ways they may be transferred from one part of the Register to the other. The regulations are to ensure that registered goods undergo a more rigorous evaluation before being approved for supply than listed goods. Clause 18 provides that the regulations may, subject to any prescribed conditions, exempt therapeutic goods from the requirement to be registered or listed. Clause 19 provides that the Secretary may allow the importation, export, or supply of therapeutic goods in Australia that are neither exempt or included in the Register, where they are for use in the treatment of another person or for use solely for experimental purposes in humans. Conditions may be attached to such approvals.

Clause 20 provides that it will be an offence for a person to knowingly or recklessly import, export, supply or manufacture therapeutic goods in Australia for human use unless they are registered, listed, or subject to an exemption or approval under clause 18 or 19 (see above). The maximum penalty for a breach of this provision will be a fine of \$24 000. It will also be an offence for a person to knowingly or recklessly import, export, or supply in Australia, therapeutic goods registered or listed in their name unless the goods have their registration or listing number on their label in the prescribed manner, or the goods are devices that are listed goods or goods manufactured in Australia for export only. The maximum penalty for breach of this provision will be a fine of \$6 000.

It will be an offence for a wholesaler to knowingly or recklessly supply in Australia therapeutic goods for use in humans unless they are registered, listed, or are subject to an exemption or approval under clauses 18 or 19 (see above). The maximum penalty for breach of this provision will be a fine of \$12 000 (clause 21).

Clause 22 provides for a number of offences and penalties relating to the registration and listing of therapeutic goods, including knowingly or recklessly breaching a condition of the registration or listing of therapeutic goods; representing therapeutic goods as included in the Register when they are not; or making a claim that they or another person can arrange the supply of therapeutic

that are not registered or listed. The maximum penalty for breach of this provision will be a fine of \$6000.

Clauses 23 and 24 deal with the procedure and required form for making an application for registration or listing of therapeutic goods, including that an application be accompanied by a prescribed application fee and a fee for the evaluation of the goods.

Matters to be considered in the evaluation of therapeutic goods for registration include whether the quality, safety and effect of the goods for the purposes for which they are to be used has been satisfactorily established, and where a step in the manufacture of the goods has been done overseas, whether the manufacturing and quality controls procedures used in making the goods are acceptable (clause 25).

The Secretary may refuse to list a therapeutic good in certain circumstances, including where the goods are not safe for the purpose for which they are to be used; the goods do not comply with prescribed quality or safety criteria; and the goods do not conform to the standard applicable to the goods (clause 26).

The Secretary may impose certain conditions on the registration or listing of therapeutic goods, including as to the manufacture of the goods and the custody, use, supply, disposal or destruction of the goods. A person in relation to whom goods are registered or listed is to allow an authorised person access to enter premises at which they deal with the goods, to inspect those premises and goods, and take samples of goods and copies of documents relating to the goods (clause 28).

The Secretary may cancel the registration or listing of therapeutic goods in certain circumstances, including where it appears to the Secretary that the quality, safety, or effect of the goods is unacceptable and that a failure to cancel registration or listing would create an imminent risk of death, serious illness or injury. Where the Secretary cancels the registration or listing of goods, the Secretary may require the holder of the registration or listing to inform the public of the cancellation or take steps to recover goods already distributed. It will be an offence for a person to knowingly or recklessly refuse or fail to comply with such a requirement. The maximum penalty for breach of this provision will be a fine of \$6000 (clause 30).

Part 4 of the Bill (clauses 34 – 42) deals with the licensing of Australian manufacturers of therapeutic goods. The regulations may exempt therapeutic goods or persons from the requirement to be manufactured by a licensed manufacturer or to be a licensed manufacturer (clause 34). Clause 35 provides that it will be an offence for a person to knowingly or recklessly carry out a step in the manufacture of therapeutic goods for use in humans without a licence unless the goods or the person are exempt. The maximum penalty for a breach of this provision will be a fine of \$24 000. In addition, it will be an offence for a holder of a licence to knowingly or recklessly breach a condition of a licence. The maximum penalty for a breach of this provision will be a fine of \$12 000. It will also be an offence, in relation to a licence application, to knowingly make

a false or misleading statement. The maximum penalty for a breach of this provision will be a fine of \$6 000.

The Minister may set principles to be observed in the manufacture of therapeutic goods for use in humans. The manufacturing principles may include the standards to be maintained, and the equipment to be used, at premises used for making therapeutic goods for use in humans, and other matters relevant to the quality, safety and use of those goods. The manufacturing principles will be subject to disallowance by Parliament (clause 36).

Clause 37 deals with the procedure and required form of an application for a manufacturing licence, including that an application is to be accompanied by a prescribed application fee. The Secretary may require an applicant to allow an authorised person to inspect the premises, equipment, processes and facilities to be used in the manufacture of the therapeutic goods.

Where the application formalities have been observed the Secretary is to grant a manufacturing licence, except in certain circumstances, including where the Secretary is satisfied that the applicant will not be able to comply with the manufacturing principles; the applicant has been convicted of an offence relating to therapeutic goods; or the applicants premises are unsatisfactory for the manufacture of the goods. Where the Secretary refuses to grant a licence, the Secretary is to give the applicant notice and reasons for the decision (clause 38).

Clause 40 provides that the Secretary may impose certain conditions on the granting of a manufacturing licence, including conditions designed to ensure the holder of the licence manufactures the goods in accordance with the manufacturing principles and any other conditions relating to the manufacture of the goods the Secretary thinks appropriate. It will be a condition of each licence that the holder ensure the therapeutic goods conform to any applicable standard and that they allow an authorised person to inspect the licensee's premises which deal with the goods and take samples.

The Secretary may revoke or suspend a manufacturing licence, including where a licence holder has been convicted of an offence against the Bill; has breached a condition of the licence; or where the annual licensing charge, or any prescribed inspection fees have not been paid within 1 month of them becoming payable (clause 41).

Clause 43 provides that an annual registration, listing and licensing charge will be payable by persons in respect to whom therapeutic goods are registered, listed, or hold a manufacturing licence.

Clauses 46 – 55 and 60 provide standard administrative provisions, including powers of authorised persons in relation to the entry and searching of premises; penalties for obstructing an authorised person or failing to answer certain questions; and for review of administrative decisions.

The *Therapeutic Goods Act 1966* will be repealed by clause 65.

References

1. Minister for Community Services and Health, *Therapeutic Goods Bill 1989 - Second Reading Speech*, 5 October 1989, p. 2.
2. Public Service Board, *Review of Drug Evaluation Procedures*, 1987, p. 27.

For further information, if required, contact the Law and Government Group.
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