1989

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

SENATE

THERAPEUTIC GOODS BILL 1989

EXPLANATORY MEMORANDUM

(Circulated by authority of the Honourable Dr Neal Blewett MP, Minister for Community Services and Health)

THIS MEMORANDUM TAKES ACCOUNT OF AMENDMENTS MADE BY THE HOUSE OF REPRESENTATIVES TO THE BILL AS INTRODUCED

15761/89 Cat. No. 89 5297 8

THERAPEUTIC GOODS BILL 1989

GENERAL OUTLINE

The Bill provides for national controls over therapeutic goods. Therapeutic goods are goods used in the prevention, diagnosis, cure or alleviation of a disease, ailment, defect or injury and include those goods which are likely to be taken to be for therapeutic use because of the way they are presented or advertised.

The provisions of the Bill apply to corporations who import, export, manufacture or supply therapeutic goods and to persons who import, export, trade interstate or provide therapeutic goods to the Commonwealth.

The major parts of the Bill cover

- the determination of standards for therapeutic goods.
- establishment of an Australian Register of therapeutic goods which are approved for import, export and supply
- licensing of Australian manufacturers of therapeutic goods.

Standards:-

The standards for the quality of therapeutic goods apply to goods for human use and for veterinary use. It will be an offence to import, export or supply a therapeutic good which does not comply with a relevant standard unless the Secretary has given written consent to the contrary.

Australian Register of Therapeutic Goods:-

The Bill provides for the assessment of therapeutic goods for human use prior to the Secretary giving approval to the sponsor to import, export or supply the goods.

Approved goods will be entered into the Australian Register of Therapeutic Goods which will consist of two parts, one part for registered goods and the other for listed goods.

Classes of goods which are required to be registered or listed will be prescribed in the Regulations.

Goods to be registered will be those requiring evaluation with regard to their quality, safety and effectiveness before being approved, whereas goods to be listed will be those of a less hazardous nature which require assessment with regard to their quality and their compliance with any official standard or other specific requirement.

Acceptance for entry on the Register will be denoted by issue of a Certificate of Registration or Certificate of Listing, as appropriate.

The Regulations will exempt certain goods from the requirement to be included on the Register.

Licensing of Manufacturers:-

The Bill provides the authority to the Secretary to license corporations which manufacture in Australia therapeutic goods for human use. The Regulations may exempt persons or classes of goods from this requirement.

In order to obtain a licence, a manufacturer must allow an authorized person to inspect the premises to ascertain compliance with written principles, primarily codes of good manufacturing practice, which are determined by the Minister. The Secretary may place conditions on the holding of a licence.

Advisory Committees:-

The Regulations will provide for expert committees to provide advice to the Minister or the Secretary on matters relating to the determination of standards and manufacturing principles and the approval of goods for supply.

Review of Decisions:-

The Bill provides for reconsideration by the Minister of initial decisions, where this is requested by a person whose interests are affected, and if necessary, for subsequent application to the Administrative Appeals Tribunal for review of the reconsidered decisions.

Drug Scheduling:-

It was originally proposed that the NH&MRC Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) would be incorporated into the legislation. However the SUSDP involves requirements for the retail storage, labelling and supply of drugs which are matters over which the Commonwealth has no specific power in the Constitution. This matter was progressed by encouraging uniform adoption of the SUSDP in State and Territory legislation and it is expected that this will eventuate in mid 1990.

Date of Commencement:-

The proposed date of commencement of the legislation is 1 March 1990.

FINANCIAL IMPACT STATEMENT

Cabinet has approved a fee structure that will recover from the industry half the costs of the therapeutics program which was approximately $15 million in 1988.

The most substantial fees will be for the evaluation of products for registration and for the inspection and licensing of manufacturers. Fees will be associated with defined standards of service and the utilization of the revenue from fees will be reviewed by a joint Industry-Government committee.

NOTES ON CLAUSES

PART I - PRELIMINARY

Clause 1 - Short Title

The short title of the Act will be the Therapeutic Goods Act 1989.

Clause 2 - Commencement

Provides that the Act shall come into operation on 1 March 1990. Collection of revenue from the associated system of fees and charges will begin on 1 July 1990. Collection of those fees which are not wholly related to delivery of a specific service is provided for in a separate Bill, the "Therapeutic Goods (Charges) Bill 1989".

Clause 3 - Interpretation

Subclause 3(1) defines a number of important terms used throughout the Bill. The more significant ones are:

- "therapeutic goods" includes goods that are represented in any way to be, or likely to be taken to be for therapeutic use, 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. The definition covers diagnostic goods for in vitro use as well as those administered to patients.

- "therapeutic use" is broadly defined and includes use in the diagnosis of disease, ailments or injuries as well as in their prevention or treatment. It also specifically extends to use in connection with contraception and testing for pregnancy.

- "Register" refers to an Australian Register of Therpeutic Goods maintained under clause 17.

- "sponsor" in relation to therapeutic goods refers to a person who exports goods from, or imports goods into, Australia, or a corporation which, in Australia, manufactures goods for supply, or the person who arranges for these things to be done.

- "supply" includes provision of goods whether free or otherwise in a wide range of stated circumstances.

- "corporation" refers to a body corporate that is a foreign corporation or a trading or financial corporation in Australia within the meaning of paragraph 51(xx) of the Constitution.

- A "standard" for therapeutic goods is constituted by an applicable monograph in the British Pharmacopoeia or British Pharmacopoeia (Veterinary) unless another standard for those goods has been specifically determined under clause 10.

- an "authorized person" may be an officer of a Commonwealth, State or Territory authority, or a member of the Australian Federal Police.

Subclause 3(2). Provides that goods are to be taken to be for human use if they are not labelled or otherwise represented to be solely for use in animals.

Subclause 3(3) requires that a list of authorised persons be published in the Gazette at least once a year. The principal roles of authorised person will be to inspect manufacture of therapeutic goods and to monitor compliance with the Bill. Subclause 3(4) ensures that provisions of this Bill do not negate, and are not negated by, provisions under other Commonwealth Acts that deal with therapeutic goods.

Circumstances in which the presentation of therapeutic goods is unacceptable from the point of view of being misleading or confusing as to the content or proper use of the goods are defined in subclause 3(5). Unacceptable presentation is a reason for refusing to register or list goods on the Register.

Subclause 3(6) identifies the annual charges for registration or listing of goods and for licensing of manufacturers as those charges provided for in the Therapeutic Goods (Charges) Bill 1989 which is to be read in conjunction with this Bill.

Clause 4 - Object of Act

The purpose of the Bill, is to provide, for the establishment and maintenance of a national system of controls relating to the quality, safety and efficacy of therapeutic goods that are used in Australia, or exported from Australia.

Clause 5 - Act to Bind Crown

The clause recognises the divisibility of the Crown and provides that the Act will bind the Crown in right of the Commonwealth, States, and Territories, but that nothing in the Act will render the Crown liable to be prosecuted for an offence.

Clause 6 - Operation of Act

This clause provides the constitutional basis for the Act viz that the Act will have effect not only to things principally done by a corporation but also to things done by a legal person in the circumstances specified.

Subclause 6(3) provides for certain State and Territory legislation relating to therapeutic goods, as specified in regulations, to co-exist with this Commonwealth legislation.

Clause 7 - Goods may be declared to be or not to be therapeutic goods

In some cases, doubt may arise as to whether particular 'borderline' types of goods should be classified as therapeutic goods or, for example, as cosmetics or foods. Some goods may have several uses, only some of which are therapeutic in purpose.

Subclauses 7(1) and (2) permit the Secretary to declare that particular goods or classes of goods are or are not therapeutic goods, or that when used or labelled in a particular way they are or are not to be regarded as therapeutic goods.

A declaration under this section takes effect on its date of publication in the Gazette or on a later date specified in the notice (subclause 7(3).

Clause 8 - Power to obtain information with respect to therapeutic goods

Subclause 8(1) allows the Secretary to require information about particular goods to be provided by the importer or supplier.

This allows necessary information to be obtained to enable a decision to be reached (under clause 7) as to whether or not the goods are therapeutic goods, or for the purpose of reviewing the status of any therapeutic goods, including those that are exempt from the requirement to be in the Register.

It is an offence to refuse to supply requested information or to provide information that is false or misleading (subclauses 8(2) and 8(3)). The penalty for such an offence will be $6,000 for a person or $30,000 for a corporation.

NOTE:

While the penalties for offences committed against the Bill by corporations are not specified in the Bill, subsection 4B(3) of the Crimes Act 1914 provides that a body corporate convicted of an offence against any law of the Commonwealth is liable for a pecuniary penalty which is 5 times the maximum pecuniary penalty imposed on a natural person for the same offence. Amounts quoted in the Bill represent the maximum penalty that may be imposed on a person.

Clause 9 - Arrangements with States etc

Subclause 9(1) provides that the Minister can make arrangements with a State or Territory Government for the carrying out of functions under this Act. Such arrangements may provide for payment to the State or Territory for work carried out (subclause 9(2)).

PART 2 - STANDARDS

Clause 10 - Determination of standards

Subclause 10(1) allows the Minister to declare, by Gazettal of an order, a standard for therapeutic goods or a class of therapeutic goods. Any such standard (commonly known as a Therapeutic Goods Order) takes precedence over a monograph in the British Pharmacopoeia or the British Pharmacopoeia (Veterinary).

Matters that may be dealt with in a Therapeutic Goods Order are specified in subclause 10(2). An Order can also be made by reference to another suitable monograph or standard.

Moreover the Minister may set out in an Order, standards or requirements for the labelling or packaging of therapeutic goods.

The Minister is required to consult with an expert committee established by the regulations before determining a standard or amending or revoking a standard (subclause 10(4)). The relevant committee is, currently, the Therapeutic Goods Committee.

Clause 11 - Date of effect of standards

Identifies the date when standards made under clause 10 take effect.

Clause 12 - Standards to be disallowable

Provides that standards under clause 10 and orders revoking, varying or modifying those standards are instruments which are disallowable by the Parliament.

Clause 13 - Special provisions relating to standards

Subclause 13(1) provides that, unless otherwise specified, a standard applies to therapeutic goods for use in humans and to therapeutic goods for use in animals.

Subclauses 13(2) and (3) set out rules of interpretation for statements made in the Pharmacopoeias. For example, subclause 13(3) requires that where a monograph in the British Pharmacopoeia (B.P.) or the British Pharmacopoea Veterinary (B.P. (Vet)) represents the standard for particular therapeutic goods, those goods must also comply with any relevant labelling or packaging requirements specified in the B.P. or B.P. (Vet); otherwise they are considered not to comply with the standard. However, any applicable requirements established under clause 10 over-ride B.P. or B.P. (Vet) requirements, if they are mutually inconsistent.

Subclauses 13(4)-13(7) clarify the order of precedence when particular standards overlap or are inconsistent with other standards.

Clause 14 - Compliance with standards

Subclause 14(1) provides that unless the Secretary consents in writing it is an offence to import, export or supply therapeutic goods which do not conform to an applicable standard (Penalty: $24,000 for a person or $120,000 for a corporation). However to allow for re-packing or re-labelling of imported goods in Australia prior to distribution, a provision is included (subclause 14(2)) to the effect that imported goods need not comply with labelling or packaging standards until the time of supply in Australia. A routine exemption from Australian labelling requirements is also provided in subclause 14(3) for goods which are exported since these requirements are developed specifically for the Australian market.

Subclause 14(4) provides that goods which do not comply with a relevant standard, and whose non-compliance has not been consented to by the Secretary, may be made prohibited imports or prohibited exports under the Customs Act 1901.

Subclauses 14(5) and (6) provide for Gazettal of decisions made by the Secretary granting consent, and for applicants to be given the reasons for a decision where consent is refused.

Consent will be given by the Secretary usually in an emergency situation such as when it is necessary to maintain supply of essential therapeutic goods.

Clause 15 - Consent may be subject to conditions etc

The Secretary may place conditions on a consent under clause 14 (subclause 15(1)), and it is an offence not to comply with the conditions (subclause 15(2)). Penalty: $12,000 for a person or $60,000 for a corporation.

PART 3 - AUSTRALIAN REGISTER OF THERAPEUTIC GOODS

Division 1 - Preliminary

This Part applies to therapeutic goods for use in humans.

Clause 16 - Forms etc. of therapeutic goods

Subclause 16(1) defines those characteristics which make certain therapeutic goods separate and distinct from other therapeutic goods. This subclause has the effect of clarifying which goods require a separate entry on the Register.

Subclause 16(2) allows the Secretary to aggregate separate and distinct goods into one group because of their common characteristics, and allows that group to be treated as one entity for the purpose of this Part of the Bill. For example, a range of catheters differing only in size could be entered in the Register as a group, instead of under a multiplicity of entries.

Clause 17 - Australian Register of Therapeutic Goods

Subclause 17(1) provides for the maintenance of an Australian Register of Therapeutic Goods for recording information on therapeutic goods for human use, as well as providing for the assessment of those goods.

Subclauses 17(2) and (3) allow the Register to be in a form determined by the Secretary and to contain 2 parts, one part for "registered" goods and the other for "listed" goods. Listed goods are less hazardous than registered goods and will be entered into the Register following less rigorous assessment. Subclause 17(4) permits the regulations to prescribe the therapeutic goods or classes of therapeutic goods required to be registered or listed and the ways goods may be transferred from one part of the Register to the other.

Clause 18 - **Exempt** Goods

Subclause 18(1) allows the regulations to exempt goods from the requirement to be registered or listed. These exemptions may be subject to conditions. Generally, exempt goods will be those which do not warrant individual assessment because of the minimal risk associated with their use. Exemptions may be revoked (subclause 18(2).

Clause 19 - Exemptions for special and experimental uses

Subclause 19(1) allows the Secretary to approve the supply of goods (which are neither in the Register nor exempt from the Register), for use in the treatment of particular persons (this is commonly known as "individual patient use") or for experimental purposes in humans (clinical trials). Conditions may be applied to such approvals.

Subclause 19(2) describes the required method and form of applications for the special approvals provided for in subclause 19(1), and requires payment of an evaluation fee in the case of applications for clinical trial approvals.

Subclause 19(3) provides that conditions on approvals granted under subclause 19(1) may relate to the charges that can be made for goods used in those circumstances. This clause provides a safeguard against special use approvals being used as a route to defacto marketing of goods and the normal evaluation process being evaded.

Subclause 19(4) requires the Secretary to notify an applicant of the decision within 28 days of its making.

Clause 20 - Offences by sponsors

Subclause 20(1) makes it an offence for a person to import, export or supply goods in Australia for use in humans unless the goods are registered or listed in that person's name; or the goods are exempt; or are the subject of an approval under Clause 19. Penalties of $24,000 for a person or $120,000 for a corporation are imposed for a contravention of this provision.

Subclause 20(2) requires registered goods or listed goods (except those specified) to have their registration number or listing number on their label in the prescribed manner. Penalties of $6,000 for a person or $30,000 for a corporation are imposed for failing to comply with this subclause. Listed devices and goods that have been manufactured in Australia for export only, are excluded from this requirement because of the practical difficulties of relabelling the many imported devices, and because an Australian list number has no validity on overseas markets for exported goods. Provision is made for the registration or listing number to be added to the labels of imported goods in Australia prior to their distribution.

Subclause 20(3) allows the Secretary to have goods which are prohibited goods under subclause 20(1), made prohibited imports or prohibited exports under the Customs Act 1901.

Clause 21 - Offence relating to wholesale supply

This clause makes it an offence for a wholesaler to knowingly or recklessly supply therapeutic goods (other than listable devices) unless the goods are registered, listed, exempt, or the subject of an approval under clause 19, and provides a penalty of $12,000 for a person or $60,000 for a corporation.

The reason for excluding supply of unlisted devices from this offence provision is that listed devices will not carry a list number on their labels and therefore a wholesaler may not know whether or not they are listed. The status of other therapeutic goods will be recognisable from their labelling and from published lists of classes of products to which exemptions apply.

Clause 22 - General offences relating to this Part

This clause creates a number of general offences and penalties relating to the registration and listing of goods. These are:

- to deliberately place a false registration number or listing number on the label of goods (subclause 22(1)).
- in connection with an application under this Part, making a statement that is, to the applicant's knowledge, false or misleading (subclause 22(2)).
- breaching a condition of the registration or listing of goods (subclause 22(3)).

- deliberately misrepresenting the status of the goods in relation to the Register (subclause 22(4)).

- a sponsor of therapeutic goods included in the Register, advertising the goods for an indication other than those accepted for their inclusion in the Register (subclause 22(5)).

- making a claim that the supply can be arranged of therapeutic goods that are neither registered nor listed (subclause 22(6)).

- breaching a condition (if any) of an exemption under subclause 18(1) or an approval under clause 19 (subclause 22(7)).

- using unregistered or unlisted therapeutic goods for experimental purposes in humans except in accordance with an approval under clause 19 (subclause 22(8).

The penalty for any of these offences is $6,000 for a person or $30,000 for a corporation.

Division 2 - Registration and Listing

Clause 23 - Applications generally

This clause establishes the procedure for making an application for the registration or listing of therapeutic goods, and the required form of the application.

Clause 24 - Applications for registration

Subclause 24(1), requires the Secretary to notify the applicant of the fee, (which is determined in accordance with the regulations), for evaluating goods for registration. If the evaluation fee is not paid within two months of when the applicant was notified, the application lapses (subclause 24(2)).

Clause 25 - Evaluation of therapeutic goods

Subclause 25(1) prescribes the matters which must be considered in the evaluation of goods for registration.

Subclause 25(2) provides that where goods have been manufactured outside Australia, the standard of manufacture can be determined by adequate evidence from a relevant overseas authority. In general, it will be expected that the standard of manufacture is comparable with that expected of Australian manufacturers of such goods. Whether the applicant has agreed to pay the costs of Australian inspectors where the Secretary considers inspection of the overseas manufacturing premises to be necessary, and whether the manufacturer has agreed to such an inspection, are matters which may be considered in evaluating whether goods manufactured overseas should be registered.

Subclause 25(3). The Secretary must notify the applicant of the decision on the evaluation of goods within 28 days of making the decision and give reasons if registration is refused. If the goods are acceptable for registration, the applicant is to be given a Register form to complete. This form summarises factual information about the product for recording on the Register and takes account of any changes in detail that have occurred since lodgement of the application.

Subclauses 25(4) and 25(5) provide that when the Secretary has received from the applicant the completed Register form a certificate of registration is to be issued. Registration is to commence on the date specified on the certificate.

Clause 26 - Listing of therapeutic goods

Subclause 26(1) describes the grounds on which listing of therapeutic goods may be refused.

Subclause 26(2) is a similar provision to subclause 25(2), except that this clause provides for matters which may be considered in deciding whether goods manufactured overseas may be listed.

When an application for listing is made, the Secretary is to notify the applicant within 28 days of making a decision and, in the case of a refusal to include the goods in the list, of the reasons for the decision. If listing is approved, listing commences on the day specified on a certificate of listing which is issued to the applicant (see subclauses 26(3) and (4)).

Clause 27 - Registration or listing number

A unique registration or listing number is assigned to goods which are entered in the Register.

Clause 28 - Conditions on registration or listing

Under this clause the Secretary may impose conditions on the registration or listing of goods relating to such aspects as the manufacture of the goods, their custody, use, supply, disposal or destruction, the keeping of records, or matters relating to the standards applicable to the goods (subclauses 28(1), (2) and (3)).

Subclause 28(4) requires the Secretary to give at least 28 days notice to the sponsor of goods on the Register of any proposed addition or change to conditions applicable to the registration or listing of goods. The purpose of this clause is to give the sponsor time to make submissions about the proposed action except where urgent action is necessary to prevent an imminent risk of death, serious illness or serious injury.

Subclause 28(5). A general condition of registration or listing of goods is that authorized persons must be allowed to enter and inspect premises at which the sponsor deals with the goods, to examine therapeutic goods and related record documents on the premises, and to take samples of the goods. This subclause should be contrasted with clauses 46 to 50 which require monitoring and offence warrants to be obtained where it is sought to enter other premises where it is thought goods are being manufactured or supplied in contravention of the Act.

Clause 29 - Duration of registration or listing

Once goods are entered in the Register, they remain registered or listed goods until action is taken to cancel their registration or listing.

Clause 30 - Cancellation of registration or listing

Subclauses 30(1) and 30(2) state the grounds on which registration or listing of goods may be cancelled by the Secretary.

Subclause 30(3) requires that when cancellation is proposed for any of the reasons stated in subclause 30(2), the sponsor of the goods must be given prior notice and a reasonable opportunity to make submissions in relation to the proposed action. In these cases the Secretary must not make a final decision about cancellation without taking the sponsor's submission into account (subclause 30(4) refers). Cancellations made under subclause 30(1), which include cancellations made in more urgent circumstances, are effective immediately. In other cases, the date of effect is to be specified in the notice of cancellation (subclause 30(5)).

The Secretary may also require the sponsor of goods whose registration or listing has been cancelled to inform the public or specified sections of the public of the cancellation, or to take steps to recover any of the goods that have been distributed. The Secretary is to publish a notice of cancellation in the Gazette as soon as practicable after concellation. It is an offence to knowingly or recklessly refuse or fail to comply with a requirement under subclause 30(6). (Penalty for a person $6,000 and or for a corporation $30,000).

Division 3 - General

Clause 31 - Secretary may require information

Subclauses 31(1) and 31(2) provide that the Secretary may require an applicant for registration or listing, or the person in whose name goods are registered or listed, to provide specified types of information about the goods concerned.

This information may facilitate assessment of applications or subsequent review of products in the Register.

Clause 32 - Inspection and variation of entries in Register

This clause provides that the Register is not to be open for public inspection. However, the person in whose name the goods have been registered or listed may obtain a copy of the entry relating to his goods on request. There is provision for the regulations to prescribe a fee for this service (subclause 32(2) refers). The reason for the Register not being publicly accessible is that its entries will contain information that is confidential to a particular product's sponsor. Clause 61 (6) provides for the release of certain non-confidential parts of Register information (which will be detailed in the regulations) to any enquirer. Such release will be subject to the Freedom of Information Act 1982 (subclause 61(10)).

Subclause 32(3) provides for amendments to be made to incomplete or incorrect entries on the Register.

Clause 33 - Publication of list of goods on Register

Under this clause the Secretary may from time to time publish a list of the therapeutic goods included on the register.

PART 4 - MANUFACTURING OF THERAPEUTIC GOODS

This Part applies to goods which are for therapeutic use in humans

Clause 34 - Exempt goods and exempt persons

Subclause 34(1) provides for regulations which exempt therapeutic goods from the requirement to be manufactured by a licensed manufacturer. Generally these are goods which, because of their method of use or history of use, represent minimal concerns, such as simple topical pharmaceutical preparations. The regulations may also exempt certain persons from the requirement to be licensed to manufacture therapeutic goods (subclause 34(2)). Generally this applies to trained persons who are preparing therapeutic goods for individuals. Subclause 34(3) provides that exemptions may be revoked.

Clause 35 - Offences relating to manufacturing and licenses

Subclause 35(1) makes it an offence for a person to carry out any step in the manufacture of therapeutic goods which are for use in humans unless the person is licensed to do so, or the person or the goods are exempt. It should be noted that "manufacture", (as defined in subclause 3(1) of the Bill) in relation to therapeutic goods, refers to producing goods, or any component or ingredient of the goods, or engaging in any part of the process of producing them or bringing them to their final state.

Subclause 35(2) requires a licence holder to comply with conditions to which the licence is subject. Conditions of licences are set out in clause 40 of the Bill. The penalty for an offence under this subclause is $12,000 for a person or $60,000 for a corporation.

Subclause 35(3) makes it an offence for a person to knowingly give false or misleading information in connection with an application for a licence to manufacture therapeutic goods. The penalty for a person is $6,000 and for a corporation $30,000.

Clause 36 - Manufacturing principles

Pursuant to subclauses 36 (1) and 36(2), the Minister may determine written principles to be observed by a manufacturer of therapeutic goods. These principles will primarily comprise the Codes of Goods Manufacturing Practice (GMP) which are developed in collaboration with the therapeutic goods industry.

Subclause 36(3) allows the Minister to seek advice on the manufacturing principles from a statutory committee which, it is proposed, will be the Therapeutic Goods Committee.

Subclause 36(4) provides that manufacturing principles are disallowable instruments under the Acts Interpretation Act 1901.

Clause 37 - Application for licence

Subclause 37(1) describes the form of, and the procedure for lodging, an application for a manufacturing licence.

The Secretary may request an applicant for a licence to supply further information and to allow authorised persons to inspect manufacturing premises and aspects of the manufacturing processes which will be used to manufacture the goods concerned (subclause 37(2)).

Clause 38 - Grant of licence

Subclause 38(1) requires the Secretary to grant a licence except for the reasons stated in the subclause. A major reason is lack of compliance with the Codes of Good Manufacturing Practice. Due to the nature of the Codes and the inspection procedure, compliance with Codes cannot be absolute and must be applied with this in mind. It is proposed that the Secretary will delegate the decisions on granting licences to the Chief Inspector of Good Manufacturing Practice.

Subclause 38(2) allows the Secretary to grant a licence under circumstances where a licence would not normally be granted. For example, although an applicant may have been refused a licence for a reason in paragraph 38(1)(f), the person may have subsequently obtained appropriate staff or facilities so that the Secretary is satisfied that the licence can be issued or re-issued as the case may be.

Subclause 38(3) provides that the applicant must be advised of whether or not the application has been successful and given reasons if the licence is refused. Particulars of the decision to approve a licence are to be published in the Gazette (subclause 38(4)).

Clause 39 - Term of licence

This clause sets the effective commencing date of a licence. A licence is perpetual unless it is suspended or revoked under clause 41.

Clause 40 - Conditions of licences

Subclause 40(1) permits the Secretary to place conditions on the granting of a manufacturing licence. Conditions may include restrictions as to the classes of goods that the manufacturer can manufacture.

Subclauses 40(2) provides that the Secretary may change, add to or remove the conditions applicable to a licence.The licence holder must be given at least 28 days to comply with the changed conditions unless urgent action is necessary (subclause 40(3)).

Subclause 40(4) is a similar provision to subclause 28(5) of the Bill and makes it an additional condition of the licence that the licence holder must ensure that manufactured goods comply with relevant standards and also allow an authorised person to inspect the licensed premises which deal with the goods and take samples.

Clause 41 - Revocation and suspension of licences

This clause provides for the revoking or suspending of a licence by the Secretary on the grounds specified in subclause 41(1). Subclauses 41(2) and 41(3) define those situations in which the Secretary must advise the licence holder of the intended revocation or suspension of the licence and allow a reasonable time for a submission to be made by the licence holder and considered before a decision is made. Decisions to suspend or cancel licences must be published in the Gazette (subclause 41(6)).

Clause 42 - Publication of list of manufacturers etc

This clause permits details of licensed manufacturers to be published by the Secretary from time to time. Details which may be published include a list of persons licenced to manufacture therapeutic goods, the types of goods each manufactures and the addresses of premises to which the licence relates. In view of the frequent use of subcontract manufacturers in the Therapeutic Goods Industry, it is desirable that the status of manufacturers is made generally available.

PART 5 - PAYMENT OF CHARGES

Clause 43 - By whom charges payable

This clause imposes an annual charge in respect of the registration or listing of therapeutic goods, and on the licensing of manufacturers of therapeutic goods.

The charges will be collected through provisions of the Therapeutic Goods (Charges) Bill 1989.

By Cabinet decision, the charges will become operative from 1 July 1990.

Clause 44 - Time for payment of charges

This clause sets out the times at which the annual charges referred to in clause 43 will become payable.

In the case of goods which are registered or listed before 1 July 1990, or manufacturers who become licensed before 1 July 1990, the first annual payment will be due on 1 July 1990.

When goods become registered or listed after 1 July 1990, the first payment is due at the time of the goods' entry in to the Register. Similarly, when manufacturers become licensed after 1 July 1990, the charge is payable on the date the licence commences.

Subsequent payments will fall due on the anniversary of the first payment or on another date in the financial year which may be set by the Secretary during the first 12 month period. The allowance for an alternative date is included so that administrative arrangements can be varied if necessary to facilitate efficient processing of payments by distributing the due dates throughout the year.

It may also be convenient to sponsor companies to have payments for all their products fall due on a particular day rather than on the anniversaries of their entry into the Register. A general provision is therefore included in subclause 44(3) for the date of payment for annual charges to be varied by agreement between the Department and the person responsible for the payments.

Clause 45 - Money to be paid into trust account

Amounts of money equal to the revenue received by the Commonwealth under the Therapeutic Goods (Charges) Bill 1989 are to be paid from the Consolidated Revenue Fund into the Therapeutic Goods Administration Trust Account.

PART 6 - MISCELLANEOUS

Clauses 46 to 51 of this Part, allow authorised persons to enter premises in circumstances other than those under which entry to premises is a condition attaching to the registration or listing of therapeutic goods (subclause 28(5)), or a condition precedent to the issue of a manufacturing licence under subclause 40(4).

Clause 46 - Monitoring compliance with Act

This clause provides that an authorised person (as defined in subclause 3(1) of the Bill) may enter premises, and exercise specified powers, in the course of investigating whether the requirements of the Bill are being complied with (subclause 46(1)). This function may be carried out either with the consent of the occupier of the premises or under a monitoring warrant issued for this purpose under clause 49 (see subclause 46(2)).

Clause 47 - Entry and search of premises - evidence of offences

This clause outlines the powers of entry and seizure exercisable by an authorised person who has reason to suspect that there is evidence of an offence against the Bill on particular premises. Evidence of the commission of an offence may be seized in accordance with procedures outlined in subclause 47(2).

Entry to the premises may be effected either with the consent of the occupier of the premises or under an offence-related warrant (subclause 47(3) and clause 50 refer).

Clause 48 - General powers of authorised persons in relation to premises

Subclause 48(1) sets out the general powers of an authorised person who enters premises to monitor compliance with the Bill under clauses 46 and 47.

Subclause 48(3) makes it an offence for a person on the premises to refuse or fail to answer an authorised person's questions or provide requested record documents as required under paragraphs 48 (1)(d) or (e). (Penalty: $3,000 for a person or $15,000 for a corporation).

Subclause 48(4) accepts that it is a reasonable excuse for a person to refuse or fail to answer a question or produce a document if by doing so the person would be likely to incriminate himself or herself.

Clause 49 - Monitoring warrants

This clause describes the procedure for obtaining a monitoring warrant. The varying steps in the procedure and the provisions of the Bill to which they relate are as follows:

Subclause 49(1) - applications may be made to a magistrate.

Subclause 49(2) - the magistrate must be satisfied by information on oath, that it is reasonably necessary for the authorised person to have access to particular premises.

Subclause 49(3) - the magistrate must be given any further information required concerning the grounds for issue of a warrant.

Subclause 49(4) - the warrant must authorise the authorised person to exercise the powers in subclause 48(1), the times at which entry is authorised, the day (up to six months after its issue) when the warrant ceases to have effect, and the purpose for which it is issued.

Clause 50 - Offence related warrants

This clause sets out the requirements for issue of an offence-related warrant. Offence warrants may be issued by a magistrate who must be satisfied, by information on oath, that there are reasonable grounds for suspecting that evidence of an offence may be on particular premises (subclause 50(2)). Any further information required by the magistrate must be provided before the warrant is issued. The warrant must state the name of the authorised person, the powers that may be exercised, the times when entry may be made, the day (up to one months from issue) when the warrant ceases to have effect, and the purpose for which it is issued (subclause 50(4)).

Clause 51 - Offence related warrants by telephone

Clause 51 is a useful provision, the purpose of which is best illustrated by an example. An authorised person may, while inspecting premises under a monitoring warrant issued under clause 49, discover that an offence is being or likely to be committed against the Bill. While the authorised person may wish to seize relevant evidence, this cannot be done unless an offence related warrant is obtained (subclause 47(3)). While this warrant is being secured, the opportunity exists for relevant evidence to be concealed or destroyed by persons on the premises. Clause 51 provides a safeguard against such behaviour by allowing an authorised person to apply to a magistrate by telephone for an offence warrant in urgent cases.

Subclauses 51(2) to (8) describe the procedures to be followed in obtaining a telephone warrant. The requirements which must be satisfied are no less stringent than those which apply where a warrant is applied for in the ordinary way (see clauses 49 and 50). If a court needed to be satisfied that a power exercised pursuant to a telephone warrant was authorised by this clause, and a warrant signed by a magistrate is not produced in evidence, the court must assume that the power was not authorised (subclause 51(9)).

Clause 52 - Identity cards

Subclause 52(1) provides for the issue of identity cards to officers who are "authorised persons" as defined under subclause 3(1) of the Bill. The identity card, which will incorporate a recent photograph of the authorised person, must be produced on request when entry to premises is made otherwise than under a warrant (subclause 52(2)).

Subclause 52(3) requires a person who ceases to be authorised to return the identity card. The penalty for not doing so is $100.

Clause 53 - Retention of material on withdrawal of applications

All material submitted in connection with applications for registration or listing of goods or for manufacturing licences may be retained by the Department if the application is withdrawn.

Clause 54 - Offences

Subclause 54(1) makes an offence against clauses 14,15, or 21 or subclauses 20(1), 35(1) and (2) an indictable offence.

Subclause 54(2) establishes that certification by the Secretary that a consent for non-compliance of goods with a standard was not given under clause 14, or that specified conditions were applicable to a consent, is to be taken as prima facie evidence in prosecution of an offence under that clause.

Subclauses 54(3), (4) and (5) provide that where a court convicts a person of a non-indictable offence against the Bill, the court may order that the therapeutic goods concerned be forfeited to the Commonwealth. The Secretary may publish a notice of such forfeiture in the Gazette, and the goods may be disposed of as the Secretary directs.

Clause 55 - Conduct by directors, servants and agents

This clause, inter alia, relates to circumstances where it becomes necessary in proceedings for offences aganst the Bill, to establish the state of mind of a body corporate in relation to particular conduct. In such circumstances it will be sufficient to show that if a director, servant or agent of the body corporate had the requisite state of mind and engaged in the relevant conduct, that the body corporate engaged in the conduct (subclause 55(1) and (2)).

Under this clause, it is a defence for the body corporate to establish that it took reasonable precautions to avoid the conduct in question.

Similarly, if the servant or agent of a person (other than a body corporate) is found to have a state of mind or engaged in conduct connected with an offence, then the state of mind and the conduct is taken to have been proved against the person.

Clause 56 - Judicial notice

Clause 56 provides that all courts are to take judicial notice of the British Pharmacopoeia and the British Pharmacopoeia (Veterinary).

Clause 57 - Delegation

Subclause 57(1) allows the Minister to delegate all or any of his or her powers and functions under the Bill. The officers to whom such delegation can be made are officers of the Department or officers in another Commonwealth Department or authority that has functions relating to therapeutic goods.

A restriction on delegation is however provided by subclause 41(2) in the case of the powers conferred by paragraph 19(1)(a). These powers may be delegated only to an officer who is registered or eligible for registration as a medical or dental practitioner, because clinical judgement is required in deciding application for permission to use an unregistered or unlisted product in individual patients.

Clause 58 - Export certifications

Subclause 58(1) provides that the Secretary may issue export certifications for goods that are for human therapeutic use.

Certification of the marketing status of a product and the standard of its manufacture is commonly required by regulatory authorities in countries to which Australian manufactured goods are exported. For medical drugs, the format of the certificates follows the recommendations of the World Health Organisation's Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. As the Commonwealth is the appropriate certifying authority under a national regulatory system, the States and Territories are required not to issue certificates of this type (subclause 58(2)refers).

A prescribed fee is payable for the issue of an export certificate and for any inspection of manufacturing premises that is necessary to enable the certificate to be issued (subsection 58(3) refers).

Clause 59 - Fees

Collection of fees under the Bill will commence on 1 July 1990.

Clause 60 - Review of decisions

This clause makes provision for the Minister and the Administrative Appeals Tribunal (AAT) to review decisions made under the Bill. A decision under this clause has the same meaning as in the Administrative Appeals Tribunal Act 1975 (subclause 60(1)). An initial decision (which subclause 60(1) defines as a decision of the Secretary under subclause 3(1), 7(1) or 14(6) or Part 3 or 4), may be reconsidered by the Minister at the written request of a person whose interests are affected by that decision. The Minister may either confirm or revoke the initial decision. Where a decision is revoked, the Minister may also substitute another decision (see subclause 60(3)).

Subclause 60(5) obliges the Minister to notify the applicant of the decision and inform the applicant that a further application may be made for a statement of reasons for the Minister's decision, and for the decision to be reviewed by the AAT (subclauses 60(6) and (8)).

Clause 61 - Release of information

This clause allows the Secretary to release information in relation to therapeutic goods that came into the Department's possession while performing its functions, to other overseas, Commonwealth, State and local bodies including committees having functions relating to therapeutic goods. The clause sets out the body or organisation to which information can be released, the type of information concerned, and the purpose served by the release of such information. Specified types of therapeutic goods information may accordingly be released to:

- The Director-General of the World Health Organisation (paragraph 61 (2)(a))

- The head of an authority of the Commonwealth, a State or a Territory having functions relating to therapeutic goods (subclause 61(3))

- The head of a national regulatory authority of another country which has national responsibility relating to therapeutic goods (subclause 61(4))

- The head of an international organisation or a national regulatory authority with which the Commonwealth has cooperative arrangements relating to the assessment or regulation of therapeutic goods (subclause 61(5)).

- A person who requests information about goods that are on the Register (subclause 61(6)). The information to be accessable in this case will be specified in the regulations and will comprise basic product information such as the name, form, description, content and sponsor of the goods.

Information may also be released to permit the safe use of a product and to give the reasons for withdrawing products (subclause 61(7)).

Subclause 61(8) allows information obtained by the Department in relation to a particular matter such as, for example, registration of therapeutic goods, to be used in consideration of other matters within its functions such as pharmaceutical benefits and public health, and to be provided by the Secretary to committees appointed to advise on those matters (including committees of the National Health and Medical Research Council (NH&MRC).

A general provision (subclause 61(9) exempts the Secretary from civil proceedings in respects of any loss, damage or injury suffered by a person as a result of the release of information in good faith pursuant to this clause.

Clause 61 is expressed to be subject to the provisions of the Freedom of Information Act 1982 (section 61(10)).

Clause 62 - Consequential amendments

A schedule to this Bill updates the title of the Therapeutic Goods Act where it is referred to in other legislation.

Clause 63 - Regulations

Subclause 63(1) provides that the Governor-General may make regulations which are not inconsistent with the Bill. The regulations may prescribe matters required by the Bill or matters necessary to give effect to the Bill (paragraph 63(1)(a) and (b)). Regulations may be made for particular matters including:

- the establishment, functions and powers, and the remuneration payable to members of committees to advise the Minister or Secretary on matters relating to therapeutic goods (paragraph 63(2)(a)).

- the prescribing of requirements for the storage, transport, advertising, sampling and testing of therapeutic goods (paragraphs 63(2)(b) to (d).

- the prescribing of fees for the testing of therapeutic goods, the inspection of manufacturing operations and the evaluation of data concerning therapeutic goods by the Department, otherwise than for the purposes of this Bill (paragraph 63(2)(g)). This allows fees to be charged when these functions are carried out at the request of another person or organisation or when supplementary evaluations are carried out on registered goods, such as when evaluating data for the extension of shelf life.

- the prescribing of penalties for offences against the regulations which do not exceed $1000 in the case of natural persons and $5000 in the case of a body corporate (paragraph 63(2)(j).

Subclause 63(3) provides for the regulations to:

- set the levels of fees associated with the administration of the Bill and to specify circumstances in which they may be refunded, reduced or waived (paragraphs 63(3)(a) and (b).

- specify the type of information to be provided annually by a holder of a manufacturer's licence (paragraph 63(3)(c)).

Subclause 63(4) allows regulations to be framed in such a way that they refer to some aspect of another document. The reference may be to a particular edition of that document or to the most recent edition as amended from time to time. An example of this would be a regulation classifying goods for a particular purpose according to whether or not they were in a schedule of the NH&MRC's Standard for the Uniform Scheduling of Drugs and Poisons (S.U.S.D.P.).

PART 7 - REPEAL AND TRANSITIONAL PROVISIONS

Clause 64 - Interpretation

The phrase "former Act", when used in this Part of the Bill, refers to the Therapeutic Goods Act 1966.

Clause 65 - Repeal

The Therapeutic Goods Act 1966 is repealed by this clause, as is intended to be replaced by the new Bill.

Clause 66 - Transitional arrangements for goods required to be registered or listed

The transitional arrangements set out in this clause are to apply to goods which are already legally available in Australia at the time of the commencement of the new Bill.

Subclause 66(2) provides that provided the sponsor of goods referred to in subclause 66(1) has not, to the Secretary's knowledge, imported the goods in contravention of the Regulations to the Customs Act 1901, and has not been convicted of an offence against Commonwealth or State/Territory law in respect of those goods during the previous two years, the sponsor will not be held to be liable to the offence of importing, exporting, manufacturing or supplying unregistered or unlisted goods, and of not having the register number on their label, in the first three months after the Bill comes into operation.

If the sponsor of established goods applies within three months of the Bill's commencement to have the goods registered or listed under the new system, s/he may continue to supply the goods for six months (or a longer specified period) without being liable to an offence under subclause 20(1), and is not required to have the Register number on the label of the goods until twelve months (or a longer specified period) after the Bill's commencement. This allows time for the applications to be made and processed, and then gives the sponsor extra time to make necessary adjustments to the product labels to include the new Register number.

Subclause 66(4) provides that a sponsor of established goods who applies to have the goods registered or listed in accordance with subclause 66(3) will not be required to pay an application fee (paragraph 66(4)(a)).

Established goods will be registered without an evaluation being carried out, so no evaluation fee is payable at that time (paragraph (b)). However, if the goods are evaluated at a later stage as part of a review of their registration the prescribed fee will be payable for that evaluation.

Subclause 66(5). The offence that relates to supply of unregistered or unlisted goods by wholesalers will not come into operation until fifteen months (or a longer specified period) after the Bill's commencement. This is because the labelling of established goods will not be amended to display the new Register number for twelve months or more after the Bill's commencement. Wholesalers will rely on the number system to identify the Register status of the therapeutic goods they are handling.

Clause 67 - Transitional provision for therapeutic goods for export only

Exporters of goods which are produced solely for an export market will have six months after the Bill's commencement in which to get these products listed on the Register. This concession is included to avoid disruption of existing and ongoing export contracts.

Clause 68 - Transitional arrangements for Part 4

The transitional arrangements set out in clause 68 are to apply to manufacturers of therapeutic goods who are already operating at premises in Australia when the new Bill comes into effect.

An established manufacturer may continue to carry out the same kind of manufacture of the same goods at the same premises for four months after the Bill's commencement without being liable to prosecution for not having a licence, providing the manufacturer has not, to the Secretary's knowledge, been convicted of an offence against Commonwealth or State/Territory law in respect of those goods during the previous two years (subclause 68(2).

Under subclause 68(3) an established manufacturer who lodges an application for a licence within four months of the Bill's commencement, may continue to operate as previously until the outcome of the application is decided.

Clause 69 - Continuation of standards and requirements

This clause provides for the continuation of standards and requirements that were in force under the Therapeutic Goods Act 1966.

Printed by Authority by the Commonwealth Government Printer