EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Regulations

ISSUED ON THE AUTHORITY OF THE MINISTER OF STATE FOR AGED, FAMILY AND HEALTH SERVICES

The commencement date of the Therapeutic Goods Act 1989 (the Act), as a consequence of an amendment in the Senate is, subject to certain provisions, the day after the proposed Therapeutic Goods Regulations (the proposed Regulations) have been formally approved by both Houses of Parliament (section 2 of the Act).

Section 4 of the Acts Interpretation Act 1901 enables the Regulations to be made prior to the commencement of the Act. The Regulations made pursuant to that provision would accordingly commence on the same day as the Act, that is the day after the Regulations are approved by both Houses.

Section 63 of the Act provides that the Governor-General may make Regulations prescribing the matters set out therein. The Regulations relate to the following matters:

(a) prescribing State and Territory legislation which can operate concurrently with the Act (subsection 6(3)). Part 1 contains a list of these laws;

(b) prescribing requirements for advertising therapeutic goods (paragraph 63(2)(o). Part 2 of the Regulations deals with this matter and defines prohibited and required representations in advertisements for therapeutic goods directed to the public;

(c) prescribing therapeutic goods which are required to be registered or listed or which are exempt from registration or listing (paragraph 17(4)(a) and subsection 18(1)). Part 3 of the Regulations defines the goods in each category and deals with the transfer of goods between the categories, provided for by paragraph 17(4)(b), or between sponsors, provided for by paragraph 63(2)(f);

(d) exempting goods or persons from the requirements of Part 4 of the Act which deals with the licensing of manufacturers of therapeutic goods (subsections 34(1)and 34(2)). Part 4 of the Regulations deals with the exemptions, matters related to conditions of holding a licence, provided for by paragraphs 40(4)(e) and 63(3) (c), and the transfer of licences, provided for by paragraph 63(2) (f);

(e) prescribing requirements for sampling and testing therapeutic goods (paragraph 63(2)(d). Part 5 of the Regulations deals with these matters;

(f) the establishment, functions and powers, and remunerations payable to members, of committees which advise the Minister or the Secretary on matters relating to therapeutic goods (paragraph 63(2)(a)). Part 5 of the Regulations deals with these matters;

(g) prescribing fees for functions carried out under the provisions of the Act including application fees for registration and listing (subsection 23(c) and paragraph 37(1)(g)), evaluation fees (paragraph 19(2)(b)(iii) and subsection 24(1)), fees for inspections of manufacturers (paragraph 63(2)(h) and a fee for providing information from the Register (subsection 32(2)). Fees also apply to services carried out at the request of a person (paragraph 63(2)(g)). Paragraph 63(3)(a) permits fees for different classes of goods or steps in manufacture.

Part 7 of the Regulations deals with these matters and with the waiver and reduction of fees provided for in paragraph 63(3)(b).

(h) prescribing information which may be released from the Register to a person (subsection 61(6)). Part 8 defines the information which can be released to a person and deals with delegations and review of decisions under the Regulations.

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

Similar regulations were made and presented to Parliament in May 1990. The Senate disallowed those Regulations to permit, amongst other things, further consultation with all affected parties. Several amendments have been included in the Regulations to reflect the outcome of this process.

As the Regulations are similar to those disallowed in May 1990, pursuant to section 48 of the Acts Interpretation Act 1S£1 section 49 of that Act may have applied to the Regulations. That section prevents the re-making of Regulations, which are the same in substance as Regulations which have been disallowed, for a period of six months unless certain other conditions are met. The period of six months referred to in that section has, however, elapsed.

Details of the Regulations are attached.

S.R. 355/90

ATTACHMENT

DETAILS OF THE THERAPEUTIC GOODS REGULATIONS

Regulation 1 of Part 1 of the Regulations provides that these Regulations may be cited as the Therapeutic Goods Regulations. They commence on the day after the Regulations have been approved by both Houses of Parliament.

Regulation 2 is an interpretations provision which defines various terms used in the Regulations.

Regulation 3 defines the State and Territory legislation which can operate concurrently with the Therapeutic Goods Act. This is necessary as a precaution against the Act inadvertently and adversely affect a State or Territory provision e\ice State and Territory controls extend further than the quality, safety and efficacy of therapeutic goods. Also it is expected that the States and Territories will implement controls at the retail level for the supply and promotion of therapeutic goods.

Part 2 of the Regulations deals with requirements for advertising of manufactured therapeutic goods for use in humans to the public. Advertising includes statements on labels, information supplied with the goods and advertisements in the print and electronic media.

Regulation 4 excludes from the provisions of Part 2 advertising to specified health care workers and wholesalers of therapeutic goods who must be provided with full information on the therapeutic uses of goods.

Schedule 1 under Regulation 4 contains a list of alternative therapy practitioner bodies whose members the alternative therapy industry considers have sufficient training to qualify for the exemption from the advertising requirements.

Regulation 5 restricts the requirements of Part 2 to goods for use in humans.

Regulation 6 prohibits advertising to the public from promoting the use of therapeutic goods for medical conditions which should be treated under medical supervision or subsequent to medical advice. These medical conditions are referred to in Schedule 2 of Regulation 8 as prohibited representations in advertisements. The Schedule also specifies other prohibited representations relating to unacceptable claims as well as required representations for specified classes of therapeutic goods, which provide for public advertising to be accurate and relevant.

The Regulation also prevents goods which can only be obtained with the prescription of a medical practitioner or a dentist or directly from a pharmacist being advertised to the public. Regulation 7 allows the Secretary to prevent a person publishing false or misleading advertisements.

Regulation 9 allows the Secretary to permit the label or information included in certain therapeutic goods to contain proscribed representations, if this is necessary for the appropriate use of the goods. For example, this allows the labelling of salbutamol nasal spray, which is available without a prescription, to indicate its use for the relief of the symptoms of asthma, an otherwise prohibited representation in public advertising.

Part 2 of the Regulations underpins self regulation of public advertising by the Therapeutic Goods Industry and to ensure consistency with the self regulatory requirements, Schedule 2 refers to clauses in the Therapeutic Goods Advertising Code of the Media Council of Australia.

Part 3 of the Regulations prescribes the therapeutic goods or the classes of therapeutic goods for use in humans which are required to be included in the Australian Register of Therapeutic Goods as registered goods or listed goods under Part 3 of the Act, or which are exempted from the requirements to be registered or listed (regulations 10,11 and 12).

Schedule 3 under Regulation 10 specifies the goods which are required to be registered. In general, drugs require registration unless listed or exempt.

Schedule 4 under Regulation 11 specifies the goods which are required to be listed. In general, therapeutic devices are required to be listed, unless registered or exempt.

Schedule 5 under Regulation 12 specifies the goods which are exempt from the operation of Part 3 of the Act.

Regulation 13 deals with the transfer of goods which are registered or listed, upon the death of the person responsible for the goods or the bankruptcy, winding up or disposal of the business of the sponsor of the goods.

Regulation 14 deals with the procedure and other requirements for transferring goods from one part of the Register to the other part. This occurs, for example, if listed goods become subject to a schedule of the Poisons Standard and consequently become registrable. The regulation allows the sponsor of the goods sufficient time to provide evidence of the suitability of the goods for registration.

Regulation 15 prescribes the manner in which the registration number or the listing number, which is assigned under Section 27 of the Act, appears on the label or the packaging of therapeutic goods. This provision enables people in the supply chain, including consumers, to know that the goods are registered or listed.

Schedule 6 under Regulation 16 specifies those therapeutic devices which, if they are manufactured overseas, require the Secretary to consider the standard of their manufacture in deciding upon an application for listing. If these goods were manufactured in Australia they would be subject to the requirement to be manufactured by a licensed manufacturer.

Part 4 of the Regulations deals with the licensing of manufacturers.

Regulation 17 exempts therapeutic goods or classes of therapeutic goods for use in humans from the requirement to be manufactured by a licensed manufacturer. The goods are specified in Schedule 7 to the Regulations.

Regulation 18 exempts certain persons, such as trained persons dispensing therapeutic goods, from the requirement to be licensed to manufacture therapeutic goods for use in humans. The classes of persons are specified in Schedule 8 to the Regulations.

Regulations 19, 20 and 21 contain requirements for licence holders and prescribe conditions upon which manufacturing licences are issued. The conditions include maintaining prescribed records of manufacture, publicly displaying the licence and notifying the Secretary of changes of key personnel involved in manufacture.

Regulation 22 deals with the transfer of the licence upon the death of the licence holder or the bankruptcy, winding up or disposal of the holder's business. The Secretary must agree to the transfer of the licence.

Part 5 of the Regulations permits official samples of therapeutic goods to be taken by officers authorised by the Secretary and for the samples to be examined, tested and analysed by official analysts. The official analysts are appointed by the Secretary to investigate compliance of the goods with standards and other requirements which are established under the Act.

Regulations 23, 24 and 25 deal with, respectively the interpretation of terms used in Part 5, the powers and duties of officers authorised to take samples and the appointment of official analysts.

Regulation 26 prescribes the method by which official samples are taken by an authorised officer and forwarded to the official analyst so as to ensure the integrity of the sample.

Regulation 27 to 29 prescribe the procedures to be followed by an official analyst. Regulation 27 prescribes the responsibilities of the official analyst. Regulation 28 prescribes relevant tests to determine that goods are of a particular standard and Regulation 29 prescribes the procedure for reporting the findings of the official analyst.

Regulations 30 prescribes the procedure and other requirements to review the finding of an official analyst, if the findings are disputed by a person who is notified of the findings of the official analyst.

Regulation 31 prescribes the payment by the Commonwealth for official samples taken bv an authorised officer.

Regulation 32 states the requirements for a person to assist and provide information to an authorised officer or an official analyst and establishes a penalty for an offence under the Regulations.

Regulation 33 requires the Secretary to issue an identity card to each authorised officer and states the responsibilities of the card holder.

Part 6 of the Regulations deals with the establishment of Committees created under the Act.

Regulation 34 establishes the Therapeutic Goods Committee which advises the Minister primarily on standards for the quality of goods, requirements for labelling and packaging and standards to be observed by manufacturers.

Regulation 35 establishes the Therapeutic Device Evaluation Committee which makes medical and scientific evaluations primarily of therapeutic devices and provides advice to the Minister or to the Secretary.

Regulation 36 established the Australian Drug Evaluation Committee which makes medical and scientific evaluations primarily **of** drugs and provides advice to the Minister or to the Secretary.

Regulation 37 allows the Minister or the Secretary to refer matters between committees established under Part 6.

Regulations 38 to 42 deal with matters relating to the administration of the Committees including tenure of office of members, responsibilities and procedures for disclosure of interests, filling vacancies and other committee rules.

Part 7 of the regulations specified the fees established under the Act. The scale of the fees is determined following advice to the Minister by an Industry-Government consultative committee which meets periodically to discuss the structure of the fees.

The fees primarily apply to applications for registration or listing of goods and for manufacturers' licences, for the evaluation of goods for registration and experimental use in humans and for the inspection of manufacturers.

The fees are presented in Schedule 9 of Regulation 43.

Regulation 44 permits the recovery of costs where an analysis of goods has been requested by a person, rather than instigated by, the Secretary under Part 5.

Regulation 45 defines situations in which the Secretary may waive or reduce the fees.

Part 8 of the Regulations deals with a number of miscellaneous items.

Regulations 46 prescribes the information held by the Register on therapeutic goods included in the Register which may be released to a person upon the request of the person.

Regulation 47 provides for the delegation of the Secretary's powers and functions under the Regulations.

Regulation 48 provides for an appellant to request a review of a decision by the Minister and if the appellant is dissatisfied with the reviewable decision, then to request a review of that decision by the Administrative Appeals Tribunal.