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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

SENATE

THERAPEUTIC GOODS AMENDMENT BILL 1991

EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Aged, Family and Health Services, the Honourable Peter Staples, MP.)

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THERAPEUTIC GOODS AMENDMENT BILL 1991

GENERAL OUTLINE

The purpose of the Bill is to amend the Therapeutic Goods Act 1989 to implement the recommendations made by Professor Peter Baume in his "Report on the Future of Drug Evaluation in Australia", which have been accepted as a package by the government. In line with those recommendations of the Baume Report that require legislative action before Autumn Sittings 1992, the Therapeutic Goods Act 1989 is to be amended to:

(a) change the object of the Principal Act to introduce an appropriate balance between, on the one hand, the need to set up a system of controls relating to the quality, safety and efficacy of therapeutic goods supplied in, or exported from, Australia, with the need, on the other hand, for timely availability of new or improved therapeutic goods;

(b) provide for the introduction of a scheme to permit greater access to experimental or unapproved therapeutic goods by terminally ill patients or patients with a life threatening illness who are seriously ill, and for the authorisation of appropriate medical practitioners to supply classes of specified unapproved therapeutic goods to certain classes of patients;

(c) enable greater reliance to be placed upon data supplied to the Therapeutic Goods Administration in support of applications to register goods in the Australian Register of Therapeutic Goods by increasing the penalties for providing false or misleading information;

(d) provide the basis for the introduction of time limits within which evaluation of drugs to be identified in the Regulations must be completed;

(e) enable sponsors to make safety-related changes, without the need for prior approval, to product information for their registered products where the changes place further restrictions on the use of the products;

(f) provide for consequential adjustments to the payment of evaluation fees to allow for the lapsing of 25% of such fees where there is a failure by the Department of Health, Housing and Community Services to meet any applicable deadlines for the completion of evaluations for drugs identified in the Regulations.

A further minor amendment has been included with the above changes which will clarify that sponsors of exported therapeutic goods need not comply with certain labelling requirements that have relevance only for the Australian market.

FINANCIAL IMPACT STATEMENT

Possible loss of some revenue in respect of evaluation fees payable by sponsors seeking to register their products. This would occur only when the Therapeutic Goods Administration should fail to meet any applicable deadlines for the completion of evaluations of mostly prescription drugs identified in the Re ulations.

NOTES ON CLAUSES

Clause 1 - Short Title

This clause provides that the short title of the Principal Act will be the Therapeutic Goods Amendment Act 1991, and identifies the Therapeutic Goods Act 1989 as the "Principal Act".

Clause 2 - Commencement

This clause provides that the Principal Act shall come into operation on the day it receives the Royal Assent.

Clause 3 - Objects of Act

The objects clause in section 4 of the Principal Act would be amended to provide a more appropriate balance between the a need of the community for therapeutic goods that meet the highest standard for quality and are safe and efficacious, with the need of the community for the timely availability of new or improved therapeutic goods in Australia.

Clause 4 - Exempt goods

Subclause 4(1) substitutes a new section 18 in the Principal Act,

New subsection 18(1) provides that the Therapeutic Goods Regulations may, subject to any conditions, specify that particular therapeutic goods, or a class of therapeutic goods, or all therapeutic goods, except those goods specified in those Regulations, may be exempted from the operation of Part 3 of the Principal Act. The proposed new category of exemption referred to in new paragraph 18(1)(a) is intended to facilitate the Special Access Scheme under which certain classes of patients, such as terminally ill patients, may gain greater access to unapproved drugs in appropriate circumstances.

New subsection 18(2) provides that where all therapeutic goods, except as specified in the Regulations, are to be exempted, the exemption will only apply to classes of persons identified in the Regulations.

New subsection 18(3) provides that where an exemption is revoked, the revocation will operate on a day stipulated by the Regulations, which must be a day not earlier than 28 days after those Regulations were made.

Subclause 4(2) is a savings provision to ensure that all Regulations made pursuant to section 18 of the Principal Act before its amendment by subclause 4(1) will continue in force as if made under section 18 as amended.

Clause 5 - Exemption for special and experimental uses

This clause inserts new provisions to enable the Secretary, in accordance with those provisions, to authorise particular medical practitioners to directly supply unapproved therapeutic goods to patients.

New subsection 19(5) provides that the Secretary is empowered to authorise a particular medical practitioner to supply either particular therapeutic goods, or a particular class of therapeutic goods to a class or classes of persons identified in the Secretary's written authority.

New subsection 19(6) provides that the Secretary's authority under new subsection 19(5) may only be given to medical practitioners who belong to a class of practitioners prescribed by the Regulations for this purpose. In addition, the recipients of the unapproved goods specified by the Secretary in his or her authorisation must belong to a class or classes of patients identified in the Regulations.

New subsection 19(7) provides that the Regulations may prescribe the circumstances in which the Secretary may grant an authority under subsection 19(5).

New subsection 19(8) provides that where the Secretary gives an authority under subsection 19(5), such action will not render the Commonwealth, the Secretary or a delegate liable to a person for any injury, damage or loss suffered by that person because of the use of the therapeutic goods by that person or any other person.

New subsection 19(9) clarifies that all references in section 19 of the Principal Act to "medical practitioner" means a medical practitioner who is registered in a State or internal Territory, as a medical practitioner.

Clause 6: Offences by sponsors

This clause makes a consequential amendment to subsection 20(1) of the Principal Act to provide that sponsors who supply goods which are the subject of an authority under new subsection 19(5) will not commit an offence for the purposes of section 20 of the Principal Act.

This clause also amends subsection 20(2) by no longer making it an offence for a sponsor to export registered goods without including the registration or listing number of those goods on their labels.

Clause 7: Offence relating to wholesale supply

This clause amends section 21 of the Principal Act to take into account the changes made to section 19 of the Principal Act by this Bill. The amendment provides that goods that are the subject of an authority granted under new subsection 19(5) are not required to be registered or listed when supplied by a wholesaler or distributor.

Clause 8: General offences relating to this Part

Paragraph 8(a) amends subsection 22(2) of the Principal Act to restrict the offence set out under that subsection to the making of false and misleading statements of a material nature in relation to applications for the listing only of therapeutic goods in the Australian Register of Therapeutic Goods. A higher penalty for an offence relating to the making of false or misleading statements relating to applications for registration of goods in the Register is provided for in new section 22A.

Paragraph 8(a) amends subsection 22(2) by omitting the reference to applications for the registration of goods in the ARTG. The penalty for knowingly or recklessly making false or misleading statements in connection with applications for registration is now dealt with in new section 22A.

Paragraph 8(b) inserts through new subsection 22(7A) a new offence under section 22 so as to require persons who have been authorised to supply unapproved therapeutic goods pursuant to new subsection 19(5) to do so only in accordance with the terms of their authority and any other prescribed requirements set out in the Regulations.

Paragraph 8(c) makes a consequential amendment to subsection 22(8) of the Principal Act (an offence provision relating to the use oftherapeutic goods which are the subject of an approval under section 19 of the Principal Act except in accordance with that approval) to refer to an authority given under subsection 19(5).

Clause 9: False statements in applications for registration

This clause inserts new section 22A which provides a penalty of $40,000 for a natural person, or $200,000 for a corporation, to knowingly or recklessly make a statement in an application to register therapeutic goods in the ARTG that is false or misleading in a material particular. The higher penalty applying to the making of false or misleading statements in applications to register therapeutic goods reflects the greater reliance that is to be placed upon claims and statements made be applicants in their applications to register goods. The Secretary will be required to make decisions about the suitability of goods for registration in the ARTG based principally upon claims made by

applicants. This is intended to reduce the time taken in checking the veracity of statements made in support of applications for registering therapeutic goods, and will enable the Department to meet the object of timely availability of new therapeutic goods for the benefit of the community, as provided for in amended section 4 of the Principal Act.

Clause 10: Applications for registration

This clause amends section 24 of the Principal Act to extend the circumstances in which an application to register therapeutic goods in the ARTG may lapse.

New paragraph 24(2)(a) has the effect of restating subsection 24(2) before its omission effected by subclause 10(1).

New paragraph 24(2)(b) provides that an application for registration under this section containing inaccurate or misleading information in a material particular will lapse.

New paragraph 24(2)(c) provides that inaccurate or misleading information of a material nature given by an applicant, or on behalf of an applicant, under this section, including information provided in response to a request to do so made under s.31 of the Principal Act, will result in that application lapsing.

New paragraph 24(2)(d) provides that an application for registration lapses if the applicant fails to comply with a requirement under section 31 of the Principal Act to provide information concerning individual patient data relating to particular therapeutic goods that are the subject of an application for registration in the ARTG.

New subsection 24(3) establishes that "individual patient data", in relation to therapeutic goods, means information derived from the conduct of clinical trials relating to individuals before, during and after the administration of goods to those persons, including information of a demographic, biochemical and haematological nature.

Subclause 10(2) provides that all the changes included in subclause 10(1) apply to applications made under section 24 of the Principal Act before the commencement of this amending Principal Act as well as to all applications made after the commencement of the amending Principal Act.

Clause 11: When evaluation fee due for payment

This clause qualifies the requirement in section 24A that the full evaluation fee is payable by an applicant on the day that fee is notified the applicant. The amendment is necessary to accommodate new section 24D which provides for the partial payment of an evaluation fee in the circumstances described in that provision.

Clause 12: Reduction of evaluation fee where evaluation not completed within prescribed period

This clause inserts new section 24D.

New subsection 24D(1) provides that this section applies only to applications for the registration of certain therapeutic goods identified in the Regulations, which will be certain drugs that are required to be evaluated within a prescribed time limit.

New subsection 24D(2) provides that, despite sections 24, 24A and 24B of the Principal Act, applicants of such drugs need only pay 75% of the evaluation fee before the completion of an evaluation of their drugs.

New subsection 24D(3) provides that where the evaluation of an applicant's goods is not completed within the prescribed time limit referred to in new subsection 24D(1), then the evaluation fee otherwise payable by the applicant pursuant to the Regulations is to be taken to be 75% of that prescribed fee.

New subsection 24D(4) provides that where the evaluation of an applicant's goods is completed within the prescribed time limit, then the applicant is liable to pay the balance of the full evaluation fee upon the completion of that evaluation.

New subsection 24D(5) provides that, for the purposes of new subsections 24D(2), (3) and (4), an evaluation is completed when the applicant is notified of the Secretary's decision under section 25(3) of the Principal Act.

Clause 13: Evaluation of therapeutic goods

This clause amends section 25 of the Principal Act to require evaluation of certain therapeutic goods identified in the Regulations to be completed within time limits to be prescribed. These will be drugs evaluated by the Drug Evaluation Branch of the Therapeutic Goods Administration.

Paragraph 13(1)(a) inserts new subsection 25(2A) that provides that an evaluation of certain therapeutic goods, as prescribed, must be completed within the period prescribed by the Regulations.

Paragraph 13(1)(b) inserts new subsection 25(6) that provides that a failure to complete an evaluation within the time limit prescribed will not render either the Commonwealth, the Secretary or any delegate liable to any person for any injury, damage or loss that should or could arise from, or be caused by, that failure.

Subclause 13(2) provides that the amendments introduced by subclause 13(1) does not apply to any applications made before the commencement of this amending Principal Act.

Clause 14: Inspection and variation of entries in the Register

Clause 14 inserts three new subsections into section 32 of the Principal Act.

New subsection 32(4) provides that where a person in relation to whom goods are registered or listed in the ARTG asks the Secretary to vary product information included in the ARTG relating to the goods, and the only effect of the variation sought would be to reduce the class of persons for whom the goods may be used or to add a warning or precaution devoid of any promotional material, then the Secretary is required to vary the entry in accordance with the request.

New subsection 32(5) provides that where a sponsor has asked the Secretary to vary information, other than information referred to in new subsection 32(4), included in the ARTG in relation to that sponsor's goods, and the Secretary is satisfied that the variation sought does not indicate any reduction in the quality, safety or efficacy of the goods for the purposes for which they are to be used, then the Secretary may vary the entry in accordance with the request.

New subsection 32(6) defines "product information", in relation to therapeutic goods, to mean information relating to the safe and effective use of a product, including information about the usefulness and limitations of the product.

Clause 15: Offences

This clause has the effect of making the offence under new section 22A an indictable offence.

Clause 16: Delegation

Paragraph 16(a) amends subsection 57(1) of the Principal Act to include a reference to another delegation power in new subsection 57(6), to clarify that the power of delegation is to be more restrictive when exercised in relation to new subsection 19(5).

Paragraph 16(b) amends subsection 57(2) by allowing the Secretary to delegate his or her powers under paragraph 19(1)(a) of the Principal Act to an officer of the Department who is registered or eligible for registration as a pharmacist in a State or internal Territory.

Paragraph 16(c) inserts new subsections 57(6) and 57(7).

New subsection 57(6) provides that the Secretary's power to authorise medical practitioners to supply unapproved therapeutic goods pursuant to new subsection 19(5) of the Principal Act may only be delegated to an officer of the Department who is registered, or eligible for registration, in state or internal Territory, as a medical or dental practitioner.

New subs ction 57(7) provides that Regulations may be made to prescribe the circumstances in which, and the requirements that must b observed, by the Secretary's delegates who may grant authorities under subsection 19(5).

Clause 17: Regulations

This clause amends section 63 of the Principal Act to insert new paragraph 63(da).

New paragraph 63(2)(da) provides that the Governor-General may make Regulations to set time limits within which evaluations, pursuant to section 25 of the Principal Act, of certain therapeutic goods, as specified in the Regulations, must be completed.