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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

THERAPEUTIC GOODS LEGISLATION AMENDMENT (ANNUAL CHARGES) BILL 2008

EXPLANATORY MEMORANDUM

(Circulated by authority of the Parliamentary Secretary to the Minister for Health and Ageing, Senator the Hon Jan McLucas)

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OUTLINE

The *Therapeutic Goods Act 1989* (TG Act) requires that a therapeutic good must be registered, listed or included in the Australian Register of Therapeutic Goods (the ARTG) before it can be lawfully imported into, manufactured in, supplied in, or exported from Australia. In addition, the TG Act generally requires a person to obtain a manufacturing licence to manufacture goods in Australia. An annual charge is payable in respect of the registration, listing or inclusion of therapeutic goods in the ARTG, and in respect of manufacturing licences issued under the TG Act.

Annual charges are considered to be taxes and, in accordance with section 55 of the Constitution, are imposed by a separate taxing Act: the *Therapeutic Goods (Charges) Act 1989* (TG Charges Act). The provisions relating to the assessment, recovery and collection of the annual charges are contained in the TG Act.

The Therapeutic Goods Legislation Amendment (Annual Charges) Bill 2008 (the Bill) amends the TG Act and the TG Charges Act to make a number of changes to the existing regime for the imposition and collection of annual charges, to provide more transparency, accountability and clarity in the granting of exemptions from liability to pay annual charges due to low turnover of therapeutic goods, and to make other technical and consequential amendments.

Amendments to the *Therapeutic Goods Act 1989*

Payment of annual charges

Section 44 of the TG Act prescribes the time for payment of annual charges. It does not set a uniform date for the payment of annual charges, and the date that a charge is payable can differ depending on a number of factors. The date that the annual charge is payable can be varied, but in most cases this can only be done with the agreement of the person liable to pay the charge.

It is administratively inefficient for both the Therapeutic Goods Administration (the TGA) and industry for annual charges for different goods to be payable on the date of the regulatory approval. To improve efficiency, the Bill proposes a system under which most annual charges are payable on the same date. Under this system:

- annual charges for goods first entered on the ARTG become payable on the day worked out under the regulations;
- annual charges for manufacturing licenses first issued during the financial year is payable at the date of commencement of the licence; and

annual charges for subsequent years become payable on a uniform date (this has been set at 1 October).

Setting a uniform date for the payment of most annual charges will result in administrative efficiencies for both the TGA and industry stakeholders, as it allows most annual charges to be levied and paid at the same time.

Reduction and Waiver of annual charges and the exemption relating to low value turnover

At present, both the TG Charges Act and the TG Act contain provisions relating to the reduction or waiver of annual charges. For consistency and readability the Bill moves the provisions relating to the reduction and waiver of annual charges to be co-located in the TG Act. Therefore, the Bill repeals the current provisions for low value low volume exemption from the TG Charges Act and the provisions are inserted into the TG Act.

In addition, the Bill introduces transparency, accountability and clarity in the application of the exemption from liability to pay annual charges because of low turnover value of therapeutic goods. The changes will ensure that persons who apply for or are granted the exemption from paying annual charges have the requisite supporting evidence that is certified by a third party. This will address the concern raised by the Australian National Audit Office in their Financial Statement Audit Report for 2006-2007 for the Department of Health and Ageing in relation to the lack of third party confirmation that the applicant does meet the eligibility criteria for the low value exemption.

In addition, the regulations for the low value exemption will cover the making of an application for that exemption, the ability to request additional information from applicants for that exemption or from those already granted exemption, cancelling the exemption and requiring payment of the annual charge and merits review of decisions by the Secretary refusing or cancelling.

Amendments to the *Therapeutic Goods (Charges) Act 1989*

The Bill inserts into the TG Charges Act a provision that annual charges under the TG Charges Act can be set at a nil amount for a particular class of goods. This amendment allows for flexibility to modify the way that certain costs are recovered by allowing for costs to be recovered by fees for services relating to particular therapeutic goods, instead of by the imposition of annual charges.

The TG Charges Act contains provisions that are intended to ensure that annual charges are payable where goods are entered on the ARTG or licensed under a State law. However, the TG Charges Act refers to provisions of the TG Act that were repealed when amendments were made to the TG Act to shore up the constitutional validity of the cooperative scheme because of the High Court's decision in *R v Hughes* (2000) 202 CLR 535. The Bill therefore updates the relevant sections accordingly.

FINANCIAL IMPACT STATEMENT

These amendments to the TG Act and TG Charges Act will have very low impact on business, individuals and economy as some of the measures proposed to be implemented, such as the uniform period for the payment of annual charges after the commencement of registration, listing or inclusion of goods in the ARTG, have already been implemented administratively.

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NOTES ON CLAUSES

Clause 1: states that the short title of the legislation is the *Therapeutic Goods Legislation Amendment (Annual Charges) Act 2008* (the Act).

Clause 2: sets the commencement date of sections 1 to 3 of the Act as the day on which it receives the Royal Assent. The amendments to the *Therapeutic Goods Act 1989* and the *Therapeutic Goods (Charges) Act 1989* set out in Schedule 1 commence on a single day to be fixed by Proclamation. If Schedule 1 is not proclaimed within 6 months of Royal Assent, it will automatically commence on the first day after that period.

Clause 3: has the effect of amending the *Therapeutic Goods Act 1989* (the TG Act) and the *Therapeutic Goods (Charges) Act 1989* (the TG Charges Act) in the manner set out in Schedule 1 to the Act.

Schedule 1—Amendments

Therapeutic Goods Act 1989

Item 1. Item 1 repeals the current section 44 and inserts a new section 44 into the TG Act. New section 44 amends the current regime that sets out the specific dates when annual charges are payable.

<u>New section 44 – Time for payment of charges</u>
Under the existing provisions, annual charges are generally payable:

- if it is the year that the entry in the Australian Register of Therapeutic Goods (the ARTG) or manufacturing licence commenced, on the date of entry in the ARTG or the date the manufacturing licence was granted;
- in subsequent years, on the anniversary of that day (current subsections 44(1) and 44(2)).

The date that the annual charge is payable can be varied but in most cases this can only be done with the agreement of the person liable to pay the charge (current subsection 44(3)).

New section 44 sets out a new payment date which in most cases prescribes a uniform date of payment of annual charges, but at the same permits some flexibility in prescribing the dates in which the annual charges are payable by allowing the Regulations to work out a different date when those charges are payable.

<u>New subsection 44(1)</u>
This subsection sets out when the annual registration charge, annual listing charge or annual charge for inclusion in the ARTG for a particular financial year becomes payable.

New paragraph 44(1)(a) provides that for goods that have been registered, listed or included in the ARTG in a financial year, the annual charge becomes payable on a day worked out under the Regulations. This regime would allow the dates for the payment of annual charges payable the first time the goods were registered, listed or included in the ARTG to be set out in the Regulations on a date after the commencement of the registration, listing or inclusion

of the goods in the ARTG. It would allow, for example, a date to be set that is one or three months after the commencement of the registration, listing or inclusion of the goods in the ARTG.

New paragraph 44(1)(b) provides that in subsequent years, that is after the first financial year that the goods were registered, listed or included in the ARTG, the annual charge is payable on a uniform date of 1 October every year, or on another day specified by the Regulations.

New subsection 44(2)

This subsection sets out when the annual licensing charge for a particular financial year becomes payable. It provides that an annual licensing charge becomes payable on the day of the commencement of the manufacturing licence and in subsequent financial years the annual charge becomes payable on 1 October of that financial year, or on another day specified in the Regulations.

New subsection 44(3)

This subsection provides that, despite any dates set or permitted to be prescribed under new subsections 44(1) and 44(2), the Secretary can specify a later day other than the date set or to be prescribed on which the annual charge becomes payable by a person for a financial year. This later date is notified to that person in writing and the notice has effect accordingly.

New subsection 44(4)

This subsection makes it clear that the operation of this section is subject to new section 44A. This means that the annual charges payable will not be payable for a particular financial year if a person is found to qualify for an exemption from the liability to pay annual charges under new section 44A. New section 44A will, for example, enable the Secretary to defer the date for paying annual charges to allow for a determination of an application for an exemption from paying annual charges for therapeutic goods included, registered or listed in the ARTG.

Therefore, subject to any other dates prescribed or subject to the Secretary exercising her discretion under new subsection 44(3), from the financial year commencing 1 July 2009 annual charges will become payable on a common date for all existing, as well as new, registrations, listings and inclusions in the ARTG, as well as manufacturing licences. These amendments also apply to grouped therapeutic goods. Grouped therapeutic goods are therapeutic goods included in a gazetted therapeutic goods group, a gazetted therapeutic devices group or a gazetted kits group. Goods within a gazetted therapeutic goods group or gazetted therapeutic devices group have common characteristics and/or are produced by the same manufacturer. A single annual charge is payable in respect of all goods included in each group of goods. New paragraph 44(1)(a) will only apply to newly registered or listed grouped goods. New paragraph 44(1)(b) will apply to existing grouped goods, even if new goods are added to the grouped goods.

Item 2. Item 2 inserts a new section 44A into the TG Act. Subsection 5(3) of the TG Charges Act currently provides for the low volume low value turnover exemption from the liability to pay annual charges. The requirements made for the purpose of this exemption are set out in regulations 4B, 4C, 4D, 4E, 4F and 5 of the TG Regulations. These provide for the making of an application for the exemption, the requirement for an application fee, the making of decision to grant the exemption, review of decisions by the Administrative Appeals Tribunal and the immediate payment of the annual charges where the applicant or the person granted an exemption based on an estimate of turnover is found to be ineligible.

This amendment moves the provisions relating to the low volume exemption from the TG Charges Act to the TG Act. For consistency and readability it is desirable for all provisions relating to the reduction and waiver of annual charges to be co-located in the TG Act.

New section 44A – Exemptions from liability to pay charges

This section provides more transparency and clarity to the application of the exemption from liability to pay annual registration charge, annual listing charge or annual charge for inclusion in the ARTG where a person's turnover of the therapeutic goods concerned is of low value. New section 44A also simplifies the criterion of the exemption to now only refer to the value of the turnover instead of the volume and value of the turnover. The current arrangement only takes into consideration the value of the turnover, and therefore the amendments reflect this current arrangement.

New subsection 44A(1)

The subsection provides that the details of the low value turnover exemption from the liability to pay annual charges are to be set out in the Regulations. The Regulations will make provisions for and in relation to the following:

(a) exempting a person from liability to pay annual registration charge, annual listing charge or annual charge for the inclusion in the ARTG for a financial year if the person's turnover of the therapeutic goods concerned for a financial year specified in the Regulations is of low value;

(b) the making of an application for an exemption and requiring payment of that charge for the current year if the application is refused; and

(c) cancelling an exemption and requiring payment of that charge for the current year.

The Regulations will also prescribe deadlines for the making of an application for exemption, when the payment for the annual charges should be made if the decision is not to grant an exemption, the cancellation of the exemption where additional information provided by the person who was granted an exemption does not support that exemption, and the lapsing of an application for the exemption if the evidence is not provided by the applicant within the allocated time.

New subsection 44A(2)

As the TGA is a cost recovery organisation it needs to recover its costs appropriately through fees and charges. New subsection 44(A)(2) allows for charging a specified fee where an application for exemption has been made. The Regulations would set out such a requirement. The application fee is a fee charged for processing the application and must not be such as to amount to taxation.

New subsection 44A(3)

This subsection provides that the Regulations may require a person, who is applying for an exemption or has been granted an exemption, to provide a statement prepared by an approved person. That statement will need to specify whether the person's turnover of the therapeutic goods concerned for the financial year concerned is of low value. The Regulations will prescribe who the approved persons are for this purpose. The approved person could include certified accountants and auditors. The approved person is intended to provide third party certification of a person's turnover of the therapeutic goods concerned.

New subsection 44A(4)
This subsection allows for the Regulations to provide that additional information or documents may be obtained from applicants seeking exemptions or from persons granted exemptions.

New subsection 44A(5)
This subsection allows for the Regulations to provide for review by the Administrative Appeal Tribunal of decisions by the Secretary to refuse applications for exemption or to cancel exemptions.

New subsection 44A(6)
This subsection provides that subsections 44A(2) to (5) do not limit the operation of subsection 44(1). This means that the regulations to be made for the purposes of subsection 44A(1) will not be limited to the prescribing of application fees, requirements to provide statements by approved persons, the obtaining of additional information and merits review process.

New subsection 44A(7)
This subsection allows for the Regulations to specify the criteria for establishing whether a person's turnover of the therapeutic goods concerned for a particular financial year will be considered of low value. This section also provides that different rules can be set out in the Regulations for different therapeutic goods.

New subsection 44A(8)
The purpose of this subsection is to make clear that new section 44A does not limit paragraph 63(3)(b) of the TG Act that enables Regulations to be made for the refund, reduction or waiving of fees or charges. That is, new section 44A will not be the only circumstance where annual charges can be waived. Waiver of annual charges can apply for example to non-profit hospital supply unit as currently set out in regulation 4A of the TG Regulations.

New subsection 44A(9)
This subsection defines the terms "approved person" and "turnover" to have the same meaning as specified in Regulations made for the purposes of this section. The meaning and scope of these terms will be set out in the Regulations.

Item 3. Item 3 provides for the application and effect of amendments made to the TG Act by Items 1 and 2.

Subitem 3(1) provides that the amendment made by Item 1 applies in relation to the financial year beginning on 1 July 2009 and all subsequent financial years. This is regardless of whether the registration, listing or inclusion in the ARTG of the therapeutic goods, or whether the manufacturing licence, commenced before, on or after 1 July 2009. For example, from 1 July 2009, new paragraph 44(1)(b) would apply to all therapeutic goods registered, listed, or included in the ARTG on or before the financial year 2008-2009. In addition, subitem 3(1) would apply, even if the commencement date of Item 1 as fixed by Proclamation is before 1 July 2009.

Subitem 3(2) provides that the amendment made by Item 2 applies for the purposes of working out whether a person is exempt from liability to pay annual registration charge, annual listing charge or annual charge for inclusion in the ARTG from the financial year

beginning 1 July 2009 and all later financial years. New section 44A will apply to existing registered, listed or included goods in the ARTG from 1 July 2009 and subsequent financial years.

Therapeutic Goods (Charges) Act 1989

Item 4. Item 4 repeals the current subsections 4(3) to (6) and inserts new subsections 4(3) to 7 into the TG Charges Act.

The TG Act contains provisions that permit corresponding State laws that mirror the TG Act to be administered by Commonwealth officers (sections 6AAA-6AAE). At present, Victoria New South Wales, and Tasmania have enacted corresponding State laws that are intended to mirror the TG Act so that the corresponding State laws will apply the same regulatory framework relating to therapeutic goods on individuals. The TG Charges Act contains provisions that are intended to ensure that annual charges are payable where goods are entered on the ARTG under a State law or where a manufacturing license is issued under a State law (current subsections 4(3), (4), (4A) and (5)). However, the TG Charges Act refers to provisions of the TG Act that have been repealed.

New subsections 4(3) to (6) now refer to the current provisions of the TG Act (sections 6AAA-6AAE) to ensure that annual charges may be collected where goods are entered in the ARTG or manufacturers are licensed under a State law, as was intended when the cooperative scheme was introduced.

<u>New subsection 4(3)</u>
This subsection provides that if registered goods are included in the ARTG due to the operation of section 6AAE of the TG Act, this section has effect as if the goods had been registered under Part 3-2 of the TG Act. In general, Part 3-2 requires that therapeutic goods must be registered or listed in the ARTG before the goods can be lawfully imported, exported, supplied or manufactured for human use in Australia.

<u>New subsection 4(4)</u>
This subsection provides that if goods known as listed goods are included in the ARTG due to the operation of section 6AAE of the TG Act, this section has effect as if the goods had been listed under Part 3-2 of the TG Act. In general, Part 3-2 requires that therapeutic goods must be registered or listed in the ARTG before the goods can be lawfully imported, exported, supplied or manufactured for human use in Australia.

<u>New subsection 4(5)</u>
The purpose of this subsection is to provide that if medical devices are included in the ARTG under Chapter 4, due to the operation of section 6AAE of the TG Act, this section has effect as if the goods had been included in the ARTG under Chapter 4 of the TG Act. Chapter 4 of the TG Act sets out the regulatory requirements applying to medical devices, including requirements relating to the inclusion of medical devices in the ARTG before they may be lawfully supplied to the general public.

<u>New subsection 4(6)</u>
New paragraphs 4(6)(a) and 4(6)(b) provide that if the Secretary issues a licence for the purposes of a corresponding State law that correspond to Part 3-3 of the TG Act, because of the operation of sections 6AAA, 6AAB or 6AAC of the TG Act, this section has effect as if

the licence had been issued under Part 3-3 of that that Act. Part 3-3 of the TG Act sets out the regulatory requirements applying to the manufacture of therapeutic goods for human use in Australia.

Subsection 4(7)
This subsection defines the terms "amount" and "Therapeutic Goods Act". The current subsections 4(1) to 4(2) provide that annual charges of such amounts as are prescribed in the Regulations are payable in respect of the registration or listing of the therapeutic goods (including grouped therapeutic goods), inclusion of medical device in the ARTG and in respect of a manufacturing licence. New subsection 4(7) provides authority to set those amounts to a nil amount.

Item 5. Item 5 repeals subsection 5(3) of the TG Charges Act because the same provisions are now included in new section 44A of the TG Act (Item 2 refers).

Item 6. Item 6 is a saving clause which provides that, despite the repeal of subsection 5(3) of the TG Charges Act, that subsection continues to apply after the commencement of this item in relation to working out whether the annual charges mentioned in that subsection are payable by persons for the financial year beginning on 1 July 2008 and all earlier financial years.