EXPLANATORY STATEMENT

Select Legislative Instrument 2011 No. 282

Therapeutic Goods Act 1989

Therapeutic Goods Amendment Regulations 2011 (No. 3)

Therapeutic Goods (Medical Devices) Amendment Regulations 2011 (No. 3)

The object of the *Therapeutic Goods Act 1989* (the TG Act) is to establish and maintain a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The Therapeutic Goods Administration (the TGA) is responsible for administering the TG Act.

Subsection 63(1) of the TG Act provides that the Governor-General may make regulations, not inconsistent with the TG Act, prescribing matters required or permitted to be prescribed by the TG Act, or necessary or convenient to be prescribed for carrying out or giving effect to the TG Act. Paragraph 44(1)(a) of the TG Act provides that the regulations may specify the dates when annual charges in relation to registered goods, listed goods, or medical devices included under Chapter 4 of the TG Act that commenced in a particular financial year are payable. Paragraph 63(2) of the Act provides that the regulations may make provision for the establishment of committees and associated matters. Paragraph 63(2)(h) of the TG Act provides that the regulations may prescribe fees in respect of matters under the TG Act or the regulations.

The purpose of the Regulations is to amend the *Therapeutic Goods Regulations 1990* (the Principal Regulations) to establish a new statutory committee to be known as the "Advisory Committee on the Safety of Medical Devices" (ACSMD).

There is currently in place a subcommittee of the Advisory Committee on Medical Devices known as the "Medical Device Incident Review Committee" (MDIRC). The MDIRC will be disbanded and a new statutory committee, the ACSMD, established. This change of status is consistent with the policy to separate pre- and post-market assessment of therapeutic goods and also bring the arrangements for the new committee in line with the TGA's other advisory committees.

The Regulations also make a number of other amendments to the Principal Regulations that are mainly of a minor and machinery nature.

The Regulations also make amendments to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Medical Devices Regulations) that are mainly of a minor and machinery nature.

Details of the amendments to the Principal Regulations are set out in Attachment A.

Details of the amendments to the Medical Devices Regulations are set out in Attachment B.

The TG Act does not specify any conditions that need to be met before the power to make the Regulations may be exercised.

The Regulations are legislative instruments for the purposes of the *Legislative Instruments Act 2003*

The Regulations come into effect on the day after registration apart from the Regulations in Schedule 2 to the amendments to the Principal Regulations which comes into effect on 1 March 2012. The amendments in Schedule 2 relate to recognising recently enacted South Australian legislation as "corresponding State law". This later date will allow the Government of South Australia to undertake further consultation regarding the application of this amendment.

Consultation

The chairs of the TGA's Advisory Committee on Medical Devices (ACMD) and its subcommittee (the Medical Device Incident Review Committee) were consulted on the establishment of the proposed Advisory Committee on the Safety of Medical Devices.

The other measures set out in the Regulations are all minor, technical and machinery in nature in relation to which no consultation was regarded as necessary as the measures do not reflect a change in the current policy intent of the relevant regulations, except in one instance where it is proposed that a further month be made available within which eligible sponsors may lodge an application to seek an exemption from annual charges otherwise payable for maintaining their therapeutic goods in the Register.

Authority: Subsection 63(1) of the *Therapeutic Goods Act 1989.*

ATTACHMENT A

Details of the *Therapeutic Good Amendment Regulations 2011 (No. 3).*

Regulation 1 provides for the Regulations to be referred to as the *Therapeutic Goods Amendment Regulations 2011 (No. 3)*.

Regulation 2 provides for the Regulations in Schedule 1 to commence on the day after they are registered and for the Regulations in Schedule 2 to commence on 1 March 2012.

Regulation 3 provides for Schedules 1 and 2 to amend the *Therapeutic Goods Regulations 1990*.

SCHEDULE 1 – Amendments commencing the day after registration

Items [1] and [2]

Prior to the commencement of the TG Act, an agreement was reached between State and Territory governments with the Commonwealth that each State and Territory would enact legislation to mirror the Commonwealth's TG Act and Regulations. This was to achieve uniform regulation of therapeutic goods throughout Australia as sole traders (ie individuals) operating solely within a State or Territory engaged in the manufacture and supply of therapeutic goods would fall outside the Commonwealth's legislative powers. Where a State or Territory completed this task, the Commonwealth would then recognise that State/Territory enactment as one adopting the Commonwealth's Act and Regulations by declaring that legislation to be "corresponding State law". Subsection 3(1) of the TG Act defines "corresponding State law" as "a State law declared by the regulations to correspond to this Act or the regulations, including such law as amended from time to time." (Under subsection 3(1) of the Act, "State" includes the Australian Capital Territory and the Northern Territory.)

The *Therapeutic Goods (Victoria) Act 1994* (currently declared to be "corresponding State law" for the purposes of subsection 3(1) of the TG Act) has recently been repealed and replaced with the *Therapeutic Goods (Victoria) Act 2010* (Vic) that now replicates the TG Act and Regulations **as amended from time to time**. In order to ensure that the updated Victorian enactment will be recognised as legislation that replicates the Act and Regulations, these enactments must be declared to be such under the Regulations, to meet the definition of "corresponding State law" in subsection 3(1) of the TG Act.

Item 1 therefore omits subregulation 3(2) of the Principal Regulations which currently declares that the previous *Therapeutic Goods (Victoria) Act 1994* is corresponding State law.

Item 2 updates the declaration in subregulation 3(3) of the Principal Regulations as to corresponding State law in New South Wales by substituting a reference to the *Poisons and Therapeutic Goods Regulations 2008 (NSW)* and including a declaration that the *Therapeutic Goods (Victoria) Act 2010* (Vic) is corresponding State law.

Items [3], [4] and [5]

Under subregulations 5Q(3), (4) and (5) of the Principal Regulations the Secretary can delegate certain powers in relation to the approval of advertisements to the Australian Self-Medication Industry Incorporated (ASMI) and the Complementary Healthcare Council of Australia (CHCA). At present the powers that can be delegated include the power to approve an advertisement and impose conditions on the approval (see regulation 5G of the Principal Regulations), and the power to withdraw an approval (see regulation 5L of the Principal Regulations) but not the power to vary any conditions imposed (see regulation 5K of the Principal Regulations). To put the matter beyond doubt, it is proposed to amend regulation 5Q to permit the Secretary to delegate to CHCA and ASMI the power to vary any conditions imposed. As the powers for the delegate approving an advertisement to notify the applicant of the outcome (see regulation 5H of the Principal Regulations) and to allocate an approval number (see regulation 5J of the Principal Regulations) are clearly consequential on the power to approve the advertisement, a specific delegation for these powers is not needed.

For this purpose, Item 3 omits the words in subregulation 5Q(2) "to approve or refuse to approve advertisements" and Item 4 omits the words in subregulation 5Q(3) "to approve or refuse to approve advertisements" and insert "in relation to".

Item 5 amends subregulation 5Q(4) to clarify the description of the Secretary's power to delegate in relation to approvals and amend subregulation 5Q(5) to make it clear that the Secretary can delegate the power under regulation 5K to vary conditions as well as under regulation 5L to withdraw an approval.

Item [6]

Item 6 inserts a new subregulation 10H(12) into the Principal Regulations so that the offence in subregulation 10H(11) of the Principal Regulations, for not returning a certificate of inclusion of a biological in the Australian Register of Therapeutic Goods (the Register) when required to do so under that provision, would become an offence of strict liability. This amendment ensures that regulation 10H, which specifies circumstances in which the person in relation to whom a biological is included in the Register is deemed to have changed (such as when a sponsor dies), is consistent with other provisions in the Regulations setting out similar strict liability offences in relation to registered or listed goods (subregulation 10A(10) of the Principal Regulations) and medical devices (subregulation 10F(10) of the Principal Regulations).

This amendment also reflects a commitment given by the Parliamentary Secretary for Health and Ageing to the Senate Standing Committee on Regulations and Ordinances on 31 May 2011 to amend regulation 10H to the above effect.

Item [7]

Regulations 16B, 16C, 16D, 16F, and 16G of the Principal Regulations set out timeframes within which certain regulatory actions in relation to processing applications for prescription medicines must be completed by reference to the number of "working days" taken. Subregulation 16A(2) of the Principal Regulations specifies periods that are to be disregarded in ascertaining the number of working days taken.

Section 31 of the TG Act was amended in 2010 (see subsections 31(1B) and 31(1C)) to provide that where a person making an application under section 23 of the Act or a sponsor making a request under subsection 9D(3) of the Act is required to make that application/request in accordance with a pre-submission planning form and chooses in that form a period of either 30 or 60 days to respond to a section 31 request by the Secretary for documents or information, then the nominated period is taken to be:

- the relevant period for any request made under subsection 31(1) in relation to that application/request; and
- "reasonable" for the purposes of that subsection.

So as to align the period nominated by the applicant/sponsor in the pre-submission planning form with the working days disregarded for the purposes of regulation 16A, Item 7 amends paragraph 16A(2)(b) to make it clear that where the applicant/sponsor has nominated a period of either 30 or 60 days then the disregarded period terminates at the end of the nominated period, irrespective of when the information or documents requested is received from the applicant/sponsor. However, if the applicant/sponsor and the Secretary agree in writing on another day to be the end the period, then that day will be the end of the period during which the working days are to be disregarded.

Items [8] and [9]

Subregulation 16A(1) of the Principal Regulations sets out the meaning of "working day". Subregulation 16A(2) of the Principal Regulations provides certain periods that are to be disregarded in ascertaining the number of working days within which certain regulatory actions in relation to applications must be completed.

Regulations 16GB, 16GC, and 16GD of the Principal Regulations set out timeframes within which certain regulatory actions in relation to applications made in relation to biologicals must be completed. The periods specified in regulations 16GB, 16GC, and 16GD are currently expressed as the number of "days" not "working days" as referred to in regulations 16A. The periods that are to be disregarded as set out in subregulation 16A(2) do not therefore currently apply to biologicals.

Items 8 and 9 therefore amend the reference to "days" in regulations 16GB, 16GC, and 16GD to "working days" to ensure that the periods to be disregarded in calculating working days set out in subregulation 16A(2) apply to certain notifications, evaluations and decisions in respect of biologicals. This will align the time frames applying to biologicals with the timeframes that apply for other therapeutic goods in relation to these activities.

Item [10]

Item 10 makes a minor drafting amendment to subregulation 38B(1) of the Principal Regulations by omitting the words "subregulation (2)" and inserting the words "subregulations (2) and (3)" to ensure that Minister's power in subregulation 38B(1) to appoint members of the Advisory Committee on Medical Devices is subject to subregulations 38(2) and (3). This brings the

subregulation into line with the other subregulations describing the powers of the Minister to appoint members of the other advisory committees established in Divisions 1, 1A, 1B, 1C, 1E and 1EA of Part 6 of the Principal Regulations.

Item [11]

Item 11 establishes a new statutory committee, to be known as the "Advisory Committee on the Safety of Medical Devices" (ACSMD).

There is currently in place a subcommittee of the Advisory Committee on Medical Devices (established under regulation 38 of the Principal Regulations) known as the "Medical Device Incident Review Committee" (MDIRC). The MDIRC will be replaced by the new statutory committee, ACSMD. This change of status is consistent with the policy to separate pre- and post-market assessment of therapeutic goods and would bring the arrangements for the new committee in line with the TGA's other advisory committees.

The functions of the ACSMD will be to advise the Minister or Secretary about the following matters:

a. the safety of medical devices;
b. the risk assessment and risk management of medical devices;
c. other matters related to medical safety or performance; and
d. any other matters referred to the committee by the Minister or Secretary (whether or not related to medical device safety).

Item [12]

Item 12 ensures that the general provisions applying to committees established under Divisions 1, 1A, 1B, 1C, 1D 1E and 1EA of Part 6 of the Principal Regulations also applies to the new statutory committee, ACSMD by inserting the reference "1DA" after "1D" in regulation 40 of the Principal Regulations.

Item [13]

Regulation 43AAA of the Principal Regulations currently provides that an annual registration charge, listing charge or charge for including therapeutic goods in the Register in relation to the financial year in which the goods are first entered on the Register must be paid by no later than the last day of the month immediately following the month when the goods were so included.

Applications for an exemption from the requirement to pay annual charges, based on a sponsor's low value, low volume turnover of the goods included in the Register in that first year must, under subparagraph 43AAC(2)(c)(ii) of the Principal Regulations, be received by the Secretary at least 21 days before the date for payment of the annual charge mentioned in regulation 43AAA. This can create administrative difficulties for sponsors and the TGA. For example, a sponsor wishing to lodge an exemption application for a product entered in the Register in the

month of September (eg on 30 September) must currently ensure that application is received by the TGA by 10 October.

Item 13 therefore extends the date for payment of the annual charge under regulation 43AAA by one month which will have the effect of allowing an additional month for the sponsor to ensure that an exemption application to the TGA is received.

Items [14], [15], [16], [17] and [18]

Paragraph 10(b) of the Principal Regulations relevantly provides for goods (and classes of goods) mentioned in Part 1 of Schedule 4 to the Principal Regulations to be included in the part of the Register for listed goods. Various items in Part 1 of Schedule 4 to the Regulations refer to the "Schedule to the Poisons Standard".

The term "Schedule to the Poisons Standard" is also used in Items: 4A(a)(iii), 8(a), 10(c) and 10A(c) of Part I of Schedule 4 of the Principal Regulations.

For the purpose of Part 1 of Schedule 4 to the Principal Regulations, the term "a Schedule of the Poisons Standard" has been historically interpreted as to include all schedules of the Poisons Standard as well as related Appendices, particularly Appendix C. This practice has been in place since the establishment of the Register.

To avoid doubt Items 14, 15, 16, 17 and 18 amend the phrase "a Schedule to the Poisons Standard" where it is mentioned in Items 3(a)(i), 4A(a)(iii), 8(a), 10(c) and 10A(c) of Part 1 of Schedule 4 of the Regulations to "a Schedule or Appendix C to the Poisons Standard".

Item [19]

Item 19 involves the insertion of "2CA' in subclause 1(2) in Part 1 of Schedule 9 to the Principal Regulations which is consequential on the amendment in Item 20.

Item [20]

Item 20 replaces items 2B and 2C in Part 2 of Schedule 9 to the Principal Regulations with amended items 2B, 2C and a new item 2CA.

Item 2B in Part 2 of Schedule 9 sets the fee for the evaluation of applications to which regulation16F or 16G apply. Item 20 replaces item 2B with a new item 2B which removes the reference to "regulation 16G". Regulation 16G applies to applications made under section 23 of the TG Act in relation to prescription medicines that do not have to be supported by clinical, pre-clinical or bioequivalence data. To the extent that such an application requires an evaluation it is covered by items 2(bj) (application fee) and 4(h) (evaluation fee) in Part 2 of Schedule 9 which total up to the same amount as item 2B ie $4540.

Item 2C in Part 2 of Schedule 9 currently sets the evaluation fee for requests under subsections 9D(1), (2) or (3) of the TG Act for variations to an entry in the Register that involve the evaluation of clinical, pre-clinical or bioequivalence data or the chemistry, quality control of the

manufacturing. Item 20 will reduce the evaluation fee set by item 2C (for requests under subsection 9D(3) to vary entries in the Register for registered or listed goods involving the evaluation of certain kinds of data) by 20 per cent. This change was to have been part of the amendments to the Principal Regulations made by the Therapeutic Goods Amendment Regulations 2011 (No. 2) which split evaluation fees for prescription medicines into separate application and evaluation fees, including introducing an application fee for requests to which item 2C applies. The reduction of the evaluation fee in item 2C by 20 per cent was inadvertently not included in those amendments and the omission is being addressed by the replacement item 2C made by Item 20.

The replacement item 2C inserted by Item 20 also excludes the references in current item 2C to requests to vary an entry in the Register under subsection 9D(1) and (2) of the TG Act. Those references are unnecessary because subsection 9D(1) requests are already covered by item 2A(a) of Part 2 of Schedule 9. To the extent that a subsection 9D(2) request does not involve any evaluation, it is also covered by item 2A(a). To the extent that a subsection 9D(2) request does involve an evaluation, it will be covered by item 2CA. The references in the current item 2C to the evaluation of the chemistry, quality control or manufacturing of registered or listed goods have also been removed as they are unnecessary.

Item 20 also inserts a new item 2CA setting a fee for a request under subsection 9D(2) of the TG Act to vary an entry on the Register which requires the evaluation of data. Such requests are currently covered by Item 2C.

SCHEDULE 2 – Amendments commencing 1 March 2012

Item [1]

South Australia has recently passed the *Controlled Substances (Therapeutic Goods and Other Matters) Amendment Act 2011* which includes an amendment to the *Controlled Substances Act 1984 (SA)*. This amendment was assented to on 3 March 2011 and would apply the Commonwealth therapeutic goods laws as a law of South Australia. In order to ensure that the updated South Australian enactment will be recognised as “corresponding State law” in subsection 3(1) of the TG Act, the South Australian law must be declared to be "corresponding State law" under the Principal Regulations.

Item 1 therefore amends paragraph 3(3)(ba) of the Principal Regulations by inserting the following legislation:

- the *Controlled Substances Act 1984* (SA); and
- the *Controlled Substances (Poisons) Regulations 2011* (SA)

ATTACHMENT B

Details of the *Therapeutic Goods (Medical Devices) Amendment Regulations 2011 (No. 3).*

Regulation 1 provides for the Regulations to be referred to as the *Therapeutic Goods (Medical Devices) Amendment Regulations 2011 (No. 3).*

Regulation 2 provides for the Regulations to commence on the day after they are registered.

Regulation 3 provides for Schedule 1 to amend the *Therapeutic Goods (Medical Devices) Regulations 2002*.

SCHEDULE 1 – Amendments

Item [1]

Regulation 5.3 of the Medical Devices Regulations refers to applications to be selected for auditing. Subparagraph 5.3 (1)(i) specifies that applications for Class III medical devices are to be selected for auditing. Paragraph 5.3 (1)(c) currently refers to -"*a medical device that is an implantable breast prosthesis containing material of fluid consistency (other than water only or a saline solution only)*" and (f) - "*a medical device that is a prosthetic heart valve*" as devices that are to be selected for auditing. The medical devices referred to in paragraphs 5.3 (1)(c) and (f) are in fact Class III medical devices. Those references are no longer required to be separately listed under subregulation 5.3(1) as they are covered by the reference to Class III medical devices in paragraph 5.3 (1)(i).

Item 1 therefore omits references to the medical devices currently referred to in paragraphs 5.3 (1)(c) and (f)

Item [2]

Paragraph 41FH(1)(a) of the TG Act and regulation 5.3 of the Medical Devices Regulations refer to selecting applications for audit. Under paragraph 41FH(1)(a) (read with regulation 5.3(1)(i)), the Secretary must select for auditing any application to include a Class III medical device in the Register unless it has been assessed under the EC Mutual Recognition Agreement (ECMRA) or the EFTA Mutual Recognition Agreement (EFTAMRA). Subregulation 5.3(3) provides that a medical device is considered to have been assessed under the ECMRA or EFTAMRA if the device is assessed by a conformity assessment body designated by the European Community or the European Free Trade Association as applicable.

The ECMRA and the EFTAMRA allows designated conformity assessment bodies to assess medical devices to Australian regulatory requirements under the Act and associated Regulations and the intention is that conformity assessment certification issued by such bodies is accepted by the TGA as a conformity assessment certificate issued under section 41EE of the TG Act.

European designated conformity assessment bodies also assess devices and issue conformity assessment certification in accordance with European Regulatory requirements, in particular Council Directive 93/42/EEC - Medical Device Directives (MDD). Conformity assessment certification issued to the requirements of the MDD does not necessarily comply with Australian requirements for conformity assessment certification as these are issued against European requirements. When determining whether to enter medical devices in the Register, it has always been TGA practice to select for audit applications with overseas conformity assessment certification issued by European designated conformity assessment bodies if the device has only been assessed in accordance with MDD requirements.

However, the definition set out in current subregulation 5.3(3) creates ambiguity as to whether all certification issued by European designated conformity assessment bodies, whether it be against Australian requirements or the MDD requirements, is considered to be have been assessed under the ECMRA or EFTAMRA.

Therefore Item 2 omits the definition set out in current subregulation 5.3(3) of the Medical Device Regulations. This will remove make explicit that devices that have only been certified by European conformity assessment bodies, to the requirements of the MDD are still required to be selected for audit under paragraph 5.3(1)(i) of the Medical Device Regulations.

Item [3]

The *Therapeutic Goods Amendment Act (2010 Measures No.1) Act 2010* amended paragraph 41FK(e) of the TG Act to remove any reliance on the Medical Device Regulations for its effect. Current regulation 5.4 of the Medical Device Regulations refers to paragraph 41FK(e) of the TG Act and therefore no longer has any operational effect.

Item 3 therefore omits regulation 5.4.

Item [4]

Section 41LB of the TG Act provides that "*Subject to sections 41LC and 41LE, an assessment fee payable by an applicant is due and payable on the day, and in the manner, specified in the regulations. "*

Item 4 omits the current provision in regulation 9.2 regarding when an application audit fee is due and payable and provides that an application is due and payable 28 days after the day that the applicant is notified of the amount of the fee. It is intended that this will be the date of the invoice sent to the applicant.