EXPLANATORY STATEMENT

Select Legislative Instrument 2011 No. 102

Therapeutic Goods Act 1989

Therapeutic Goods Amendment Regulations 2011 (No. 2)

Therapeutic Goods (Medical Devices) Amendment Regulations 2011 (No. 2)

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

Subsection 63(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted to be prescribed by the Act, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The purpose of the Regulations is to increase certain fees in the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) by 3.4 per cent and to prescribe classes of medicines for the purposes of paragraph 3(5)(ca) of the Act.

The Regulations also make changes to the collection of application and evaluation fees for prescription medicines and make other amendments that are mainly of a minor and machinery nature.

Fees and charges increases

The increase of fees in the TG Regulations applies to application fees for registration or listing of therapeutic goods in the Australian Register of Therapeutic Goods (the Register), and to evaluation fees, to application fees for manufacturing licences and export certificates, to clinical trial notification fees and to inspection fees for manufacturing premises. The increase of fees in the MD Regulations applies to fees in relation to conformity assessments of medical devices, to applications for including medical devices in the Register and in relation to conformity assessment certificates.

The 3.4 per cent increase of fees is a general composite increase calculated using a formula agreed between the TGA and industry associations. Fees were last increased in July 2010. The increase is comprised of 50 per cent of the Labour Price Index from September 2009 to September 2010 and 50 per cent of the Consumer Price Index for the same period. The increases to fees have been rounded to the nearest $10 for amounts less than $10,000 and to the nearest $100 for amounts of $10,000 or more. Fees of $140 or less for items have not changed.

The increases to fees, taken together with the increase to charges in the changes to the *Therapeutic Goods (Charges) Regulations 1990* (the subject of a separate Minute), are expected to increase the total of fees and charges collected by the TGA by $3.5 million to $118.3 million in the 2011-12 financial year. The increases enable the TGA to recover its costs in administering the Act and to continue to meet the Government's Cost Recovery Guidelines.

"Unacceptable" presentation of medicines
Under paragraph 3(5)(ca) of the Act, the presentation of medicines in a class of medicines prescribed in the regulations will be "unacceptable" if the label of the medicines does not contain an advisory statement required in relation to that medicine by a legislative instrument made by the Minister under subsection 3(5A) of the Act.

If the presentation of therapeutic goods is unacceptable, the Secretary of the Department of Health and Ageing may refuse, under section 25 or 26 of the Act, to register or list goods the subject of an application for registration or listing in the Register, or applicants for listing under section 26A of the Act may be unable to certify that the presentation of the medicine is not unacceptable. Affected medicines would then, need labels that contained an advisory statement set out in the legislative instrument made under subsection 3(5A) of the Act in relation to medicines of that kind.

The prescribing of medicines for this purpose, being medicines principally for which a prescription is not required, assists consumers to be informed about important information relating to the safety of relevant medicines and to make informed decisions about using those products.

Other amendments
The Regulations also amend the TG Regulations in relation to a number of other, separate matters, including:

- providing for separate application and evaluation fees in relation to prescription medicines but at a rate that, together, do not exceed the level of the current evaluation fee (these fees also incorporate the increase of fees outlined above); and
- change the way in which evaluation fees paid in relation to the applications for variations to the entry of prescription medicines in the Register are collected to provide for reimbursement of 25 per cent to an applicant if the decision on the application is not made within the period set by the Regulations.

The Regulations also amend the MD Regulations to enable the Secretary to request information from specified persons (such as applicants for inclusion of a kind of medical device in the Register) about a number of matters in relation to which applicants are required to certify about under section 41FD of the Act.

Details of the amendments to the TG Regulations are set out in Attachment A and details of the amendments to the MD Regulations are set out in Attachment B.

The Act specifies no 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 commence on 1 July 2011.

Consultation

The prescribing of classes of medicines required to comply with the legislative instrument made by the Minister under subsection 3(5A) of the Act in relation to the setting out of advisory statements on labels has not been the subject of consultation as these changes reflect the status quo in relation to the requirement for labels of relevant medicines to contain warning information. Industry will be consulted about any proposal to make an instrument under subsection 3(5A) of the Act.

The measures set out in the amendments to the TG Regulations relating to the collection of application fees for prescription medicines for the period 1998 to 2000 and 2003 to the date of commencement reflect government policy then in place that resulted from negotiations between the Government and the relevant industry peak body and that was implemented with industry agreement.

The TGA consulted with industry on its 2010-11 financial forecast and outlook for financial year 2011-12 in bilateral meetings held between 16 and 25 February 2011. These meetings provided an opportunity for industry to present relevant information to be taken into account as part of the TGA's assessment and estimate of its regulatory workload and costs for financial year 2011-12.

The TGA and industry associations agreed in the past to use an indexation model to adjust fees and charges annually (with additional increases to be justified to industry), in line with cost and wage movements in the public sector. That indexation model is comprised of 50 per cent of the Australian Bureau of Statistics' wage-cost index, which reflects average wage cost movements, and 50 per cent of the Consumer Price Index. The 3.4 per cent increase in fees that are effected by the amendments to the TG Regulations and the MD Regulations are be consistent with the TGA-industry agreement on increases to fees and charges.

Industry has also been consulted about the amendments to the TG Regulations to specify particular application and evaluation fees for prescription medicines as part of business process reforms recently undertaken by the TGA.

The amendments to the TG Regulations involving references to the expertise of members of the Advisory Committee on Medical Devices and the removal of the grounds of inefficiency as a basis for removal of a member of an advisory committee established under Divisions 1 – 1E of the TG Regulations, and the amendments to the MD Regulations to clarify the Secretary's powers to order the disposal of unused emergency medical devices, were made following feedback received from the Senate Committee on Regulations and Ordinances in 2010 and earlier this year respectively.

The other measures set out in the amendments to the Regulations are minor and machinery in nature, in particular correcting outdated references to external committees and provisions of the Act and replacing references to patient information documents with references to consumer medicine information documents to enhance the clarity of the legislation and making small increases to the maximum number of members that can be appointed to the Advisory Committee on Prescription Medicine and the Advisory Committee on the Safety of Medicines. As such, no consultation was undertaken in relation to those measures.

ATTACHMENT A

DETAILS OF THE *THERAPEUTIC GOODS AMENDMENT REGULATIONS 2011 (No. 2)*

Regulation 1 – Name of Regulations
This regulation provides for the Regulations to be referred to as the *Therapeutic Goods Amendment Regulations 2011 (No. 2).*

Regulation 2 – Commencement
This regulation provides for the Regulations to commence on 1 July 2011.

Regulation 3 – Amendment of *Therapeutic Goods Regulations 1990*
This regulation provides for the Schedule to amend the *Therapeutic Goods Regulations 1990* (the Principal Regulations).

Schedule 1 –Amendments

Item [1] – Regulation 2, definition of *Complementary Medicines Evaluation Committee*

This item removes the definition of the *Complementary Medicines Evaluation Committee* from regulation 2 of the Principal Regulations. This committee was replaced by the Advisory Committee on Complementary Medicines following the commencement of Schedule 2 to the *Therapeutic Goods Amendment Regulations 2009 (No. 6)* on 25 January 2010.

This item also adds to regulation 2 definitions for *complementary medicines* and *designated active ingredient*. These definitions are the same as the definitions of those terms omitted from the Act following the commencement of the provisions contained in Part 2 of Schedule 7 to the *Therapeutic Goods Amendment (2009 Measures No. 2) Act 2009*. Part 2 of Schedule 7 to that amending Act repealed the previous Part 6-4 of the Act which had contained those definitions.

The inclusion of definitions for these terms reflects a commitment made by the Therapeutic Goods Administration (the TGA) to respond to stakeholder concern about the absence of clarity in the legislation over the meaning of the terms.

Item [2] – Regulation 2, definition of *Therapeutic Goods Advertising Code*

This item replaces the current definition of *Therapeutic Goods Advertising Code* in regulation 2 with a new definition that reflects the inclusion in the Act in 2009 by the *Therapeutic Goods Amendment (2009 Measures No. 1) Act 2009* of a specific provision dealing with the Minister's power to make the Therapeutic Goods Advertising Code.

The new definition of this term in regulation 2 refers to the code made by the Minister under section 42BAA of the Act.

Item [3] – Regulation 2, after definition of *trade name*

This item includes in regulation 2 a definition of *traditional use* in relation to designated active ingredients. This definition is related to the definitions above for *complementary medicines* and *designated active ingredients* and is the same as the definition for *traditional use* that was omitted from the Act following the commencement of the provisions contained in Part 2 of Schedule 7 to the *Therapeutic Goods Amendment (2009 Measures No. 2) Act 2009*. Part 2 of

Schedule 7 to that amending Act repealed the previous Part 6-4 of the Act which had contained that definition.

Item [4] – Regulation 2, note

This item amends the *note* at the end of regulation 2 to indicate that the definition for "product information" is now located in subsection 3(1) of the Act.

That note currently says only that definitions of "medicine" and "poison" are set out in the Act (at subsection 3(1)). As a definition for "product information" is now located in subsection 3(1) of the Act as a result of changes introduced to the Act by the *Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010*, the note needs to be updated.

Item [5] – Paragraph 3(3)(e)

This item introduces a minor formatting change to paragraph 3(3)(e) in order to accommodate new paragraph, 3(3)(f), which is added by item [6].

Item [6] – After paragraph 3(3)(e)

This item introduces a new paragraph 3(3)(f) to add the *Medicines, Poisons and Therapeutic Goods Regulation 2008 (ACT)* to the list of corresponding State laws set out in subregulation 3(3), being State (including Territory) laws declared to correspond to the Act or the Principal Regulations.

Item [7] – After regulation 3

Unacceptable presentation of therapeutic goods – prescribed class of medicine

This item inserts a new regulation 3AA to prescribe the classes of medicines for the purposes of paragraph 3(5)(ca) of the Act. These are medicines for supply in Australia other than:

- products of a kind mentioned in Part 1 of Schedule 10 to the Principal Regulations; or
- medicines the labels of which do not contain an advisory statement as required by the instrument to be made under subsection 3(5A) of the Act but for which the Secretary has given her consent under sections 14 and 14A of the Act for the medicine to be imported into, exported from or supplied in, Australia, without that advisory statement and which comply with the terms of the Secretary's consent under those provisions.

The effect of the amendment made by this item are that medicines other than medicines in these classes have to include advisory statements on their labels as set out in any legislative instrument made by the Minister under subsection 3(5A) of the Act in order to avoid the presentation of those medicines being taken to be "unacceptable".

The legislative instrument under subsection 3(5A) of the Act will reflect the current TGA document *Required Advisory Statements for Medicines Labels* (RASML).

Under current arrangements, all medicines must be supplied with labels that comply with the requirements of RASML, unless otherwise exempted. This requirement is currently imposed by Therapeutic Goods Order 69 – *General Requirements for Labels for Medicines* (TGO 69) (a standard determined by the Minister under section 10 of the Act), the requirement for therapeutic goods the subject of an application for registration or listing to comply with applicable standards (see paragraphs 25(1)(f), 26(1)(f) and 26A(2)(d) of the Act), and the requirements set out under Schedule 4 to the Regulations and under the Poisons Standard.

The coverage by TGO 69 of a number of prescription medicines is not considered appropriate, as access to such medicines is controlled by registered medical practitioners and risk-benefit profiles relating to the use of such medicines may vary considerably from patient to patient.

The effect of this amendment is to exclude prescription medicines and also medicines such as radiopharmaceuticals, medical gasses and dialysis solutions, from the requirement to include RASML advisory statements as these are not supplied directly to consumers.

Also excluded are medicines that are the subject of the consent of the Secretary under sections 14 and 14A of the Act regarding the inclusion of label advisory statements. The exclusion of these medicines is intended to ensure that applicants for the listing of medicines under section 26A of the Act are not precluded from certifying that the presentation of their medicine is acceptable if the medicine predominantly (but not fully) complies with RASML and if the Secretary has consented to the import into, export from or supply in, Australia, of the medicine notwithstanding any relevant non-compliance.

The amendment made by this item therefore reflect the objective of mandatory label advisory statements which is to assist consumers to make informed choices from the most appropriate medicines available for self-medication, and to use that medicine in a safe and effective manner.

Item [8] – Subregulation 9B(4), definition of *product information*

This item omits the definition of *product information* in subregulation 9B(4), which states that *product information* has the meaning given by subsection 9D(5) of the Act.

Following the commencement of changes introduced to the Act by the *Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010*, the definition of *product information* has, as mentioned in item [4] above, been relocated from subsection 9D(5) to subsection 3(1) of the Act and, as such, the definition of this term in subregulation 9D(5) is no longer correct.

The amendment in item [4] above, by amending the note at the end of regulation 2, indicates that a definition for *product information* is located in subsection 3(1) of the Act.

Item [9] – Subregulation 15(1)

This item replaces the reference in subregulation 15(1) to paragraph 20(2)(a) of the Act with a reference to subsections 19D(3) and (4) of the Act.

Subregulation 15(1) currently requires that the registration or listing number of therapeutic goods be set out on the label of the goods in the manner specified in regulation 15 "For the purposes of paragraph 20(2)(a) of the Act".

The reference to paragraph 20(2)(a) of the Act in subregulation 15(1) is no longer correct as subsection 20(2) was repealed by the *Therapeutic Goods Amendment Act (No. 1) 2006* (the 2006 Act), which introduced a range of measures relating to sanctions including civil penalties as an alternative measure to offences.

Prior to the 2006 Act, it was an offence under paragraph 20(2)(a) for a person in relation to whom therapeutic goods were registered or listed to import the goods into, or supply the goods

in, Australia, unless the registration or listing number of the goods was set out on the label of the goods in the prescribed manner.

The 2006 Act removed the offence at paragraph 20(2)(a) and introduced civil penalty provisions relating to the same conduct as that covered by 20(2)(a), at subsections 19D(3) and (4) of the Act.

This item updates subregulation 15(1) by replacing the now redundant reference to paragraph 20(2)(a) of the Act with a reference to subsections 19D(3) and 19D(4) of the Act.

Item [10] – Subregulation 15A(1)

This item replaces the reference in subregulation 15A(1) to the TGA guideline document "Australian Guideline For Pharmacovigilance Responsibilities Of Sponsors Of Registered Medicines Regulated By Office of Prescription Medicines" with a reference to the updated name for that document, "Australian Guideline For Pharmacovigilance Responsibilities".

Item [11] – Subregulation 35B(1)

This item amends subregulation 35B(1) to increase the maximum possible number of members of the Advisory Committee on Prescription Medicines (the ACPM) from 25 to 32.

This measure ensures that the membership of the ACPM reflects the broad range of areas of expertise listed in paragraphs 35B(2)(a) to (l) of which a member of that committee must have expertise in at least one field of expertise.

This measure helps ensure that the range of expertise of members available to attend any particular meeting of the ACPM can be as broad as possible (including, for example, where some members may be unable to attend a meeting), so that the committee can provide full and comprehensive advice to the Minister and the Secretary on relevant matters.

Item [12] – Subregulation 36B(2)

This item makes a minor change to subregulation 36B(2) by adding "of the committee" after "member" in relation to the Advisory Committee on Non-prescription Medicines.

This drafting change brings the wording of subregulation 36B(2) into line with the other relevant provisions in Divisions 1 to 1E of Part 6 that set out the fields of expertise required for members of the external advisory committees established under those Divisions (being, subregulations 34B(2), 35B(2), 37B(2) (see item [14] below), 38B(2) and 39B(2)).

Item [13] – Subregulation 37B(1)

This item amends subregulation 35B(1) to increase the maximum possible number of members of the Advisory Committee on the Safety of Medicines (the ACSOM) from 12 to 15.

This measure ensures that the membership of the ACSOM reflects the broad range of areas of expertise listed in paragraphs 37B(2)(a) to (j),of which a member of that committee must have expertise in at least one.

This measure help ensure that the range of expertise of members available to attend any particular meeting of the ACSOM may be as broad as possible (including, for example, where some members may be unable to attend a meeting), so that the committee can provide full and comprehensive advice to the Minister and the Secretary on relevant matters.

Item [14] – Subregulation 37B(2)

This item makes a minor change to subregulation 37B(2) by adding "of the committee" after "member" in that provision in relation to the Advisory Committee on the Safety of Medicines.

This drafting change brings the wording of 37B(2) into line with the wording of the other relevant provisions in Divisions 1 to 1E of Part 6 that set out the fields of expertise required for members of the external advisory committees established under those Divisions (being, subregulations 34B(2), 35B(2), 36B(2) (see item [12] above), 38B(2) and 39B(2)).

Item [15] – Subregulation 38B(2)

This item makes a minor change to subregulation 38B(2) to add the words "at least" after the words "expertise in" in that provision.

Under subregulation 38B(2) currently, each member of the Advisory Committee on Medical Devices (the ACMD) must have expertise in one of the fields listed at paragraphs 38B(2)(a) to (f).

However, the equivalent provisions in Divisions 1 to 1E of Part 6 that set out requirements relating to the fields of expertise for members of the external advisory committees established under those Divisions state that members must have expertise in "at least 1" of the listed fields of expertise.

When the Principal Regulations were amended in 2009 (with the *Therapeutic Goods Amendment Regulations 2009 (No.6)*) to replace a number of external advisory committees with new committees (including the ACMD), the words "in at least" were inadvertently left out of subregulation 38B(2).

The Senate Committee on Regulations and Ordinances expressed concern about the absence of that wording in subregulation 38B(2). The amendment responds to that concern and corrects the unintended omission.

Item [16] – Subregulation 39B(3)

This item makes a minor change to subregulation 39B(3) to add the words "at least" after the words "expertise in" in that provision.

Under subregulation 39B(3) currently, at least four of the members of the Advisory Committee on Complementary Medicines must have clinical experience in one of the fields listed in paragraphs 39B(2)(a) to (k).

However, the equivalent provisions in Divisions 1 to 1E of Part 6 that set out requirements relating to expertise for members of the external advisory committees established under those Divisions state that relevant members must have expertise in "at least 1" of the listed fields of expertise.

The change brings the wording of subregulation 39B(3) into line with the wording of those equivalent provisions (being, subregulations 34B(2), 35B(2), 36B(2), 37B(2), 38B(2) (see item [15] above) and 39B(2)).

Item [17] – Paragraphs 41C(1)(d), (e) and (f)

This item amends subregulation 41C(1) to remove "inefficiency" as a grounds upon which the Minister may terminate the appointment of a member of any of the external advisory committees established under Divisions 1to 1E of Part 6.

When changes were made to the Principal Regulations by the *Therapeutic Goods Amendment Regulations 2009 (No.6)* in relation to a number of external committees, the Senate Committee on Regulations and Ordinances expressed concern that this ground of termination might give rise to uncertainty, and that removing that ground clarify the operation of the termination power at regulation 41C.

Item [17] omits "inefficiency" as a ground for termination to address the Committee's concerns.

Item [18] – Subregulation 42(6)

Subregulation 42(6) currently requires that when an advisory committee established under Divisions 1 to 1E of Part 6 is making a determination about a member who has, under subregulation 42(4), disclosed that he or she has a direct or indirect material personal interest (whether pecuniary or not) in a matter being considered by the committee, the member (and any other member) who has a direct or indirect pecuniary interest in the matter must not be present during the committee's deliberation about the disclosure or take part in the committee's decision in that regard.

The reference in subregulation 42(6) to "direct or indirect pecuniary interest" is inconsistent with the broader requirement in subregulation 42(4) for committee members to disclose direct or indirect material personal interests (whether pecuniary or not).

Item [18] amends subregulation 42(6) to replace the reference to "pecuniary interest" with a reference to "material personal interest (whether pecuniary or not)".

Item [19] – Subparagraph 42C(1)(a)(v)

Subparagraph 42C(1)(a)(v) currently provides that the Medical Industry Association of Australia may nominate a member of the Therapeutic Goods Advertising Code Council which is established under regulation 42A.

This item replaces the reference in subparagraph 42C(1)(a)(v) to the "Medical Industry Association of Australia" with a reference to the "Medical Technology Association of Australia" to reflect a change of name of that organisation.

Item [20] – Subparagraph 42C(1)(b)(ii)

Subparagraph 42C(1)(b)(ii) currently provides that the Advertising Federation of Australia may nominate a member of the Therapeutic Goods Advertising Code Council which is established under regulation 42A.

This item replaces the reference in subparagraph 42C(1)(b)(ii) to the "Advertising Federation of Australia" with a reference to the "Communications Council" to reflect a change of name of that organisation.

Item [21] – Paragraph 42C(1)(f)

Paragraph 42C(1)(f) currently provides that the Australian Publishers Bureau and the Outdoor Advertising Association of Australia may jointly nominate a member of the Therapeutic Goods Advertising Code Council which is established under regulation 42A.

This item replaces the reference in paragraph 42C(1)(f) to the "Australian Publishers Bureau" with a reference to the "Publishers' Advertising Advisory Bureau" to reflect a change of name of that organisation.

Item [22] – Subregulations 42N(1) and (3)

This item replaces the references in subregulations 42N(1) and (3) to "pecuniary interest" with "material pecuniary interest (whether pecuniary or not)".

The effect of this change is to harmonise the disclosure of interest requirements relating to members of the Therapeutic Goods Advertising Code Council with those applying in relation to members of the advisory committees established under Divisions 1 to 1E, and the Advisory Committee on Medicines Scheduling and Advisory Committee on Chemicals Scheduling established under Divisions 3A and 3B, of Part 6 of the Principal Regulations.

Item [23] – Subregulation 42T(1)

Subregulation 42T(1) currently provides that the Complaints Resolution Panel (established under regulation 42R) has eight members, with that membership comprised according to paragraphs 42T(1)(a) to (d).

This item amends subregulation 42T(1) to increase the membership of the Complaints Resolution Panel from 8 to 9 so as to accommodate an additional member (see item [25] below).

Item [24] – Paragraph 42T(1)(b)

This item amends paragraph 42T(1)(b) which currently provides that two members of the Complaints Resolution Panel be persons nominated by the bodies referred to at subparagraphs 42T(1)(b)(i) and (ii). Item [24] amends paragraph 42T(1)(b) to refer to three members rather than two, in order to accommodate an additional Panel member (see item [25] below).

Item [25] – After subparagraph 42T(1)(b)(ii)

This item inserts a new subparagraph 42T(1)(b)(iii) into regulation 42T. The effect of this change be to provide for an additional member of the Complaints Resolution Panel (see also items [23] and [24] above), being a person nominated by the Medical Technology Association of Australia.

Items [26] and [27] – Subregulation 42T(1A)

Subregulation 42T(1A) currently requires the chairperson of the Complaints Resolution Panel to nominate an additional member to attend a meeting of the Panel at which a complaint about an advertisement or generic information relating to a medical device or other therapeutic goods is to be considered.

Item [26] amends subregulation 42T(1A) to allow (rather than require) the chairperson of the Panel to nominate an additional member for a meeting of the Panel at which a relevant complaint is to be considered. Item [27] also amends subregulation 42T(1A) to replace the

current reference in that subregulation to "medical device or other therapeutic goods" with a reference to "therapeutic device".

The effect of these changes is that the chairperson of the Complaints Resolution Panel could nominate an additional member to attend a Panel meeting if a complaint about a therapeutic device were to be considered at that meeting. By inclusion of a person nominated by the Medical Technology Association of Australia as a member (see items [23], [24 and [25] above), the Panel will have the expertise to consider complaints about medical devices, but might need assistance in relation to therapeutic devices (which include goods such as medical gloves, bandages and syringes) on an ad hoc basis where complaints about such devices are to be considered.

Item [28] – Subregulation 42T(2)

Subregulation 42T(2) currently prevents a person from being nominated as a member of the Complaints Resolution Panel if that results in more than 4 members of the Panel also being members of the Therapeutic Goods Advertising Code Council.

This item amends subregulation 42T(2) to increase the number of Panel members who may also be members of the Therapeutic Goods Advertising Code Council from four to five to reflect the increase in the membership of the Panel (see items [23], [24] and [25] above).

Item [29] – Subregulation 42Y(1)

This item makes a minor change to subregulation 42Y(1) of the Principal Regulations to remove the reference to subregulation 42Y(2) of the Principal Regulations which is removed (see item [30] below).

Item [30] – Subregulation 42Y(2)

Subregulation 42Y(2) currently requires member nominated under subregulation 42T(1A) to be present for a quorum at a meeting of the Complaints Resolution Panel at which a complaint about a medical device or other therapeutic goods is to be considered.

As the membership of the Complaints Resolution Panel is to be expanded to include a person nominated by the Medical Technology Association of Australia (see items [23], [24] and [25]) this provision is no longer necessary. This item therefore omits subregulation 42Y(2).

Item [31] – Subregulations 42ZB(1) and (3)

This item replaces the references in subregulations 42ZB(1) and (3) to "pecuniary interest" with "material pecuniary interest (whether pecuniary or not)".

The effect of this change is to harmonise the disclosure of interest requirements relating to members of the Complaints Resolution Panel with those applying in relation to members of the advisory committees established under Divisions 1 to 1E, and the Advisory Committee on Medicines Scheduling and Advisory Committee on Chemicals Scheduling established under Divisions 3A and 3B, of Part 6 of the Principal Regulations (and, following the changes set out at item [22] above to members of the Therapeutic Goods Advertising Code Council).

Item [32] – After paragraph 42ZCAI(4)(a)

This item amends subregulation 42ZCAI(4) by inserting a new paragraph 42ZCAI(4)(ab). This change enables the Complaints Resolution Panel to recommend to the Secretary that the

registration or listing of therapeutic goods the subject of a complaint about an advertisement or generic information that contravenes the Act, the Principal Regulations or the Therapeutic Goods Advertising Code be suspended where the person responsible does not comply with a request by the Panel or breaches an undertaking given to the Panel.

This change updates subregulation 42ZCAI(4) to reflect the amendment made to the Act in 2009 by the *Therapeutic Goods Amendment (2009 Measures No. 1) Act 2009* to give the Secretary power under section 29D of the Act to suspend as well as cancel the registration or listing of therapeutic goods.

Item [33] – Paragraph 42ZCAI(4)(b)

This item replaces the current reference in paragraph 42ZCAI(4)(b) to "paragraph 30(2)(e)" of the Act with a reference to "section 30" of the Act.

The effect of paragraph 42ZCAI(4)(b) is that the Complaints Resolution Panel may, in relation to an advertisement or generic information about a listed or registered therapeutic good the subject of a complaint to the Panel, recommend to the Secretary that the registration or listing of the goods be cancelled under paragraph 30(2)(e) of the Act where the person responsible does not comply with a Panel request or an undertaking given to the Panel is breached.

Paragraph 30(2)(e) of the Act is not however the only grounds set out in section 30 of the Act under which the Secretary may cancel the registration or listing of therapeutic goods in relation to advertising (see paragraphs 30(1)(f) and 30(1A)(c) of the Act). The effect of the change is that the recommendation of the Panel can cover each of the grounds in section 30 of the Act on which the Secretary can cancel the registration or listing.

Item [34] – Regulation 43AAJ, heading

Regulation 43AAJ operates to reduce the annual charge payable for a manufacturing licence if the turnover of therapeutic goods of the holder of the licence is not more than the amount specified in paragraph 43AAJ(1)(b).

The specified amount is to be increased in accordance with a general increase of TGA fees and charges of 3.4 per cent (subject to the TGA's rounding policy) for financial year 2011-12, from $78,600 to $81,300. Item [34] amends the heading of regulation 43AAJ to refer to charges reduced if annual turnover is not more than a specified amount, rather than referring in the heading to a particular amount. This ensures that the heading is consistent at all times with the relevant applicable threshold amount.

Item [35] – After subregulation 43A(2)

This item inserts a new subregulation 43A(3), with the following effect:

- where an application was made under section 23 of the Act to which item 4 of Part 2 of Schedule 9 to the Principal Regulations applied (these are mainly prescription medicines); and
- to the extent that an application fee was payable under paragraphs (c) or (d) of item 2 of Part 2 of Schedule 9 as those items operated at any time during the relevant period (between 1 August 1998 and 23 March 2000 and between 1 July 2003 and the commencement of the new subregulation 43A(3)) in relation to that application, that fee was not paid; and
- that application resulted in goods being included in the Register,

the application fee is taken not to have been payable in relation to the application.

During the periods 1998 to 2000 and from 1 July 2003, the policy adopted for administrative convenience and implemented with the industry's agreement was not to charge a separate application fee for the processing of applications made to the TGA for the registration of prescription medicines. To ensure full cost recovery, the level of the fee payable for the evaluation by the TGA of those applications was set so as to recover the cost to the TGA of application processing. An "application" fee was however payable where no evaluation fee was paid (because the application was either rejected or withdrawn prior to evaluation). Thus, the total amount of the evaluation and "application" fees collected under the policy are roughly the same as the total amount that are payable if both an application fee and, where relevant, an evaluation fee, had been collected.

The effect of the amendment that are made by item [35] are to ensure that any application fees that applied during the relevant period (but were not paid) are taken not to have been payable. This outcome is consistent with the fact that the appropriate overall level of fees was paid during the relevant period and ensures the legal effectiveness of applications processed and accepted for registration during that period.

The "relevant period" referred to above is:

- the period from the coming into operation of regulation 4 of the *Therapeutic Goods Regulations (Amendment) 1998*, No. 247 on 1 August 1998 to the coming into operation of item 5 of Schedule 1 to the *Therapeutic Goods Amendment Regulations 2000 (No. 1)*, No. 29 on 23 March 2000; and
- the period from the coming into operation of item 20 of Schedule 1 to the *Therapeutic Goods Amendment Regulations 2003 (No. 2)*, No. 151 on 1 July 2003 to the commencement of this regulation.

Item [36] – Regulation 43AA

Regulation 43AA currently provides that the amount of the fee payable under Schedule 9 to the Principal Regulations for an application to the Secretary to vary an entry in the Register under subsection 9D(3) of the Act to which regulation 16D applies, is the amount of the relevant evaluation fee, reduced by 25 per cent. The remaining 25 per cent is only payable by the applicant if the applicant is notified of the decision in relation to the application within the period specified in subregulation 16D(3) (being, either 175 or 225 days, depending on the circumstances).

Applications to which regulation 16D apply relate to requests under subsection 9D(3) of the Act for the Secretary to vary an entry in the Register for a prescription medicine that involve the evaluation of clinical, pre-clinical or bioequivalence data. The fee is set out at item 2C of Part 2 of Schedule 9.

Item [36] replaces the current regulation 43AA with a new regulation 43AA that requires the Secretary to refund 25 per cent of the evaluation fee payable under Schedule 9 for an evaluation under subsection 9D(3) of the Act to which regulation 16D applies (being, the fee at item 2C of Schedule 9) only if an applicant has paid the whole of that fee and the Secretary has notified the person of the relevant decision but not within the period required under subregulation 16D(3).

The effect of the regulation is that a person making an application under subsection 9D(3) of the Act for a variation of an entry in the Register for a prescription medicine involving the evaluation of clinical, pre-clinical or bioequivalence data must pay the full amount of the

evaluation fee at item 2C of Schedule 9 when that fee is due and payable, with 25 per cent of the fee repayable if a decision on the application is not notified within the period set by the regulations.

Item [37] – Subregulation 46(3)

This item omits subregulation 46(3) from the Principal Regulations.

Subregulation 46(3) enables, for the purposes of subsection 61(6) of the Act, the Secretary to release via the *Gazette* therapeutic goods information to a person, on application by that person, relating to the evaluation of therapeutic goods by the Australian Drug Evaluation Committee.

This committee has been replaced by the Advisory Committee on Prescription Medicines (the ACPM) under changes introduced by the *Therapeutic Goods Amendment Regulations 2009 (No.6)*.

The reference to the evaluation of therapeutic goods in subregulation 46(3) might now be confusing as the ACPM's function is to provide advice to the Minister and the Secretary in relation to prescription medicines. The Secretary, not the ACPM, is responsible for evaluating under section 25 of the Act goods that are the subject of an application for registration. Moreover, sufficient power exists in the Act to allow the release by the Secretary of relevant information from the ACPM.

As subregulation 46(3) is redundant it is considered appropriate to remove it from the Principal Regulations.

Item [38] – Schedule 9, Part 1, subclause 1(2)

This item amends subclause 1(2) of Part 1 of Schedule 9 to add a reference to item 2C of Part 2 of Schedule 9.

Under this amendment, an application under subsections 9D(1), (2) or (3) of the Act for a variation of an entry in the Register in relation to a medicine listed in Part 1 of Schedule 10 to the Principal Regulations (prescription medicines or medicines not supplied directly to consumers such as radiopharmaceuticals) involving the evaluation of clinical, pre-clinical or bioequivalence data, or the chemistry, quality control or manufacturing of the goods, are taken to be a "submission" within the meaning of subclause 1(3) of Part 1 of Schedule 9.

The effect of this change is that where a person makes more than one such application at the same time in relation to goods that contain the same active ingredient, the applications are taken to be one "submission". Taken together with the change to item 2C of Part 2 of Schedule 9 set out in item [42] below, the effect is that for such applications there is only one fee payable under item 2C rather than a separate fee for each application.

This ensures consistency with the treatment of multiple applications made by the same applicant in relation to goods having the same active ingredient for medicines mentioned in Part 1 of Schedule 10 elsewhere in Part 2 of Schedule 9 such as for paragraph (a) of item 2A (application fee for varying an entry in the Register in relation to a registered medicine mentioned in Part 1 of Schedule 10), item 2B (fee for the evaluation for the chemistry, quality control or manufacturing process of a medicine where regulation 16F or 16G applies to the application) and item 4 (fees for evaluations under section 24 of the Act in relation prescription medicines etc).

Item [39] – Schedule 9, Part 2, item 2, paragraph (ba), columns 2 and 3

This item replaces the current paragraph (ba) of item 2 of Part 2 of Schedule 9 with new paragraphs (ba) to (bh) which sets out new application fees for the purposes of paragraph 23(2)(a) of the Act for medicines to which item 4 of Part 2 of Schedule 9 applies (being, applications fees in relation to the registration of prescription medicines) with specified amounts.

These new application fees correspond to, and complement, new evaluation fees set out at item 4 of Part 2 of Schedule 9 (see items [44] to [51], [53] and [54] below). The new application fees at paragraphs (ba) to (bh) of item 2 (and the new evaluation fees to be set out in item 4) also incorporate the 3.4 per cent general increase in TGA fees for financial year 2011-12.

The effect of the changes set out at items [39] and items [44] to [51], [53] and [54], taken together, are to set new application and evaluation fees for prescription medicines that are calculated at the rate of 20 per cent and 80 per cent, respectively of the existing evaluation fees applying in relation to these medicines. As such, the overall level of both sets of fees, taken together, are, subject to the application of the 3.4 per cent general increase mentioned above, the same as the current applicable evaluation fees.

This approach (of collecting separate application and evaluation fees) is intended to replace the previous practice of not collecting a separate application fee for the processing of applications made to the TGA for the registration of prescription medicines but collecting an evaluation fee that was set at a level so as to also recover the cost to the TGA of application processing.

Item [40] – Schedule 9, Part 2, item 2A

This item amends item 2A of Part 2 of Schedule 9 by replacing the reference to subsections 9D(1), (2) and (3) of the Act in that item with a reference to section 9D of the Act.

Following the commencement of changes to the Act made by the *Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010*, additional subsections have been included in section 9D covering requests for variations to entries in the Register for kinds of medical devices. The amendment that is made by this item ensures that all the relevant subsections in section 9D are covered.

Item [41] – Schedule 9, Part 2, after item 2AB

This item inserts a new item 2AC into Part 2 of Schedule 9, which sets out an application fee for the making of an application to the Secretary under subsection 9D(3) of the Act to which regulation 16D applies.

The effect of this amendment is that where a sponsor of a registered goods applies to the Secretary under subsection 9D(3) of the Act for the Secretary to vary the entry in the Register in relation to the goods, and where that application involves the evaluation of clinical, pre-clinical or bioequivalence data, the sponsor is required to pay the application fee specified at new item 2AC of Part 2 of Schedule 9, in addition to the evaluation fee set out at existing item 2C of Part 2 of Schedule 9.

Item [42] – Schedule 9, Part 2, item 2C

This item make an amendment to item 2C of Part 2 of Schedule 9 by including a reference to a "submission".

As noted in relation to item [38] above, under subclauses 1(2) and (3) of Part 1 of Schedule 9 where a person makes more than one application at the same time in relation to goods that contain the same active ingredient, the applications are taken to be one "submission" for the purpose of determining the fees payable in relation to those submissions.

The effect of the amendments that are made by item [38] to subclause 1(2) and by item [42] to item 2C, is that there is only one fee payable under item 2C in relation to an evaluation of the kind described for multiple applications rather than a separate fee under that item for each application made in relation to therapeutic goods that contain the same active ingredient.

Item [43] – Schedule 9, Part 2, item 4

This item omits the reference to "(if paragraph (ba) of item 2 does not apply)" from item 4 of Part 2 of Schedule 9.

The effect of this change is to make it clear that the evaluation fees set out at item 4 of Part 2 of Schedule 9 are payable as well as the corresponding new application fees set out at item [39] above.

Items [44] to [51], [53] and [54] – Schedule 9, Part 2, item 4, paragraphs (a), (aa), (b), (bb), (c), (d), (g) and (h)

Item 4 of Part 2 of Schedule 9 currently sets out evaluation fees for the purposes of subsection 24(1) of the Act, being fees for the evaluation of therapeutic goods (mainly prescription medicines) the subject of applications for registration involving specified matters such as the evaluation of a new chemical entity or an extension of indications for a product.

These evaluation fees correspond to, and complement, new application fees set out at paragraphs (ba) to (bh) of item 2 of Part 2 of Schedule 9 (see item [39]). The new evaluation fees at item 4 (just like the new application fees to be set out in paragraphs (ba) to (bh) of item 2) also incorporate the 3.4 per cent general increase in TGA fees for financial year 2011-12.

The effect of the changes set out at items [44] to [51], [53] and [54], taken together with the changes at item [39], is to set new application and evaluation fees for these goods (mainly prescription medicines) that are calculated at the rate of 20 per cent and 80 per cent respectively of the existing evaluation fees applying in relation to these medicines. As such, the overall level of both sets of fees, taken together, is, subject to the application of the 3.4 per cent general increase mentioned above, the same as the current applicable evaluation fees.

This approach (of collecting separate application and evaluation fees) is intended replace the previous practice of not collecting a separate application fee for the processing of applications made to the TGA for the registration of prescription medicines but collecting an evaluation fee that was set at a level so as to also recover the cost to the TGA of application processing.

Item [52] – Schedule 9, Part 2, item 4, paragraphs (e) and (f)

Item [52] omits paragraphs (e) and (f) from item 4 of Part 2 of Schedule 9.

Item 4 sets out the fees payable in relation to the evaluation under section 24 of the Act of applications made under section 23 of the Act for the registration of prescription medicines. As a result of amendments made to the Act by the *Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010* applications are no longer made for changes to product information (the same effect is achieved by making a request for a variation to an entry in the Register under section

9D of the Act). Moreover, changes to consumer patient information are not made by way of an application under the Act. Paragraphs (e) and (f) of item 4 of Part 2 of Schedule 9 are therefore redundant. They are to be omitted by item [52].

Item [55] – Schedule 9, Part 2, item 9AC, column 2

Item 9AC of Part 2 of Schedule 9 currently sets a fee for the inspection of manufacturing premises or operations for the preparation of human blood of blood components (other than haematopoietic progenitor cells) under a manufacturing licence at a site covered by the licence that is not the primary site. Primary sites are defined in subregulation 3(4) of the *Therapeutic Goods (Charges) Regulations 1990* as the principal premises in the capital city of each State and Territory where human blood and blood components are manufactured.

Following the commencement in February 2010 of amendments to the Act made by the *Therapeutic Goods Amendment (2009 Measures No. 1) Act 2009* to replace multi-site manufacturing licences with predominantly single site licences, many manufacturing sites for the manufacture of human blood and blood components that are not primary sites are now covered by single site licences rather than by multi-site licences with a primary site.

Item [55] has the effect of ensuring that the inspection fee set out at item 9AC continues to apply to the inspection of manufacturing sites for the manufacture of human blood of blood components (other than haematopoietic progenitor cells) that are not primary sites, whether those sites are covered by single or multi site licences. The amount of the fee payable is not changed by this item.

Item [56] – Schedule 9, Part 2, item 12

This item ensures that there is no overlap in coverage between item 12 of Part 2 of Schedule 9 (which refers to the evaluation of data for the purposes of section 9D of the Act for variations to entries in the Register) and other items in that Part (such as item 2B) which provide for fees for the evaluation of data in relation to applications made under that section.

Item [57] – Schedule 10, Part 1, heading

This item replaces the current heading of Part 1 of Schedule 10, which refers to "Evaluation by the Office of Prescription Medicines", with a new heading "Evaluation by the Office of Medicines Authorisation of prescription and other medicines".

This change reflects the fact that from 1 July 2010 the Office of Prescription Medicines is known as the Office of Medicines Authorisation (OMA).

The new heading refers to "other medicines" to reflect that, within the TGA, OMA is responsible for the evaluation of other medicines as well as those listed in Part 1 of Schedule 10.

Item [58] – Schedule 10, Part 1, item 14

This item replaces the current item 14 of Part 1 of Schedule 10. The effect of this change be to update item 14 to reflect the fact that the Office of Prescription Medicines is now known as the Office of Medicines Authorisation and it is responsible for the evaluation of prescription and other medicines.

Item [59] – Schedule 10, Part 3, heading

This item replaces the current heading of Part 3 of Schedule 10, which refers to "Evaluation by the Office of Non-Prescription Medicines" with a new heading "Evaluation by the Office of Medicines Authorisation of non-prescription and other medicines".

This change reflects the fact that from 1 July 2010 the Office of Non-prescription Medicines is known as the Office of Medicines Authorisation.

The new heading refers to "non-prescription and other medicines" in order to reflect that, within the TGA, OMA is responsible for the evaluation of other medicines as well as those listed in Part 3 of Schedule 10.

Item [60] – Schedule 10, Part 3, item 5

This item replaces the current item 5 of Part 3 of Schedule 10. The effect of this change is to update item 5 to reflect that the Office of Non-prescription Medicines is known as the Office of Medicines Authorisation and is responsible for the evaluation of non-prescription medicines.

Item [61] – Schedules 12 and 13

This item omist the reference to the definition of *product information* in section 9D of the Act currently in the fourth dot point of the first paragraph of Schedule 12, and also omits the reference to that definition currently in the fourth dot point of the first paragraph of Schedule 13.

item [61] is necessary because, as part of changes introduced to the Act by the *Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010*, the definition of *product information* that was previously set out in section 9D of the Act has been relocated to subsection 3(1) of the Act.

Item [62] Schedule 14, heading

This item replaces the current heading of Schedule 14 so that it refers to regulation 2 rather than section 52F of the Act.

Section 52F of the Act (along with the rest of the previous Part 6-4 of the Act) was repealed on 25 January 2010 following the commencement of the provisions set out in Part 2 of Schedule 7 to the *Therapeutic Goods Amendment (2009 Measures No. 1) Act 2009*.

Schedule 14 lists designated active ingredients for the purposes of the definition of that term which was previously set out at section 52F of the Act but which is included in regulation 2 by item [1] above.

Item [63] – Further amendments

This item increases fees in regulation 45 and Part 2 of Schedule 9 by 3.4 per cent, subject to the TGA's rounding policy. This increase affects fees relating to a range of matters, including application fees for registration or listing on the Register, application fees for manufacturing licences, evaluation fees, clinical trial notification fees, application fees for export certificates and inspection fees for manufacturing premises.

The fees listed in item [63] do not include the new application and evaluation fees for prescription medicines set out, respectively, at items [39] and [44] to [51], [53] and [54], as these fees have been calculated to include the 3.4 per cent general increase.

This item also increases the amount specified in paragraph 43AAJ(1)(b) by 3.4 per cent, subject to the TGA's rounding policy, to $81,300.

These increases enable the TGA to recover its costs in administering the Act and to continue to meet the Government's Cost Recovery Guidelines.

ATTACHMENT B

DETAILS OF THE *THERAPEUTIC GOODS (MEDICAL DEVICES) AMENDMENT REGULATIONS 2011 (No. 2)*

Regulation 1 – Name of Regulations
This regulation provides for the Regulations to be referred to as the *Therapeutic Goods (Medical Devices) Amendment Regulations 2011 (No. 2).*

Regulation 2 - Commencement
This regulation provides for the Regulations to commence on 1 July 2011.

Regulation 3 – Amendment of *Therapeutic Goods (Medical Devices) Regulations 2002*
This regulation provide for Schedule 1 to amend the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Principal Regulations).

Schedule 1 – Amendments

Item [1] – Before regulation 8.1

Section 41JA of the Act allows the Secretary to require specified person being:

- applicants or holders of conformity assessment certificates relating to a kind of medical device or person who have held a conformity assessment certificate for a specified period; and
- persons in relation to whom a kind of medical device is included in the Register, applicants for inclusion of a kind of medical device in the Register or persons in relation to whom medical devices were included in the Register during a specified period,

to provide information or documents about specified matters, including, at paragraph 41JA(1)(j), matters prescribed by the regulations for the purposes of that paragraph.

Under section 41FD of the Act the applicant for the inclusion of a kind of medical device in the Register must certify as to a range of matters in relation to devices of that kind. Section 41JA of the Act does not however currently authorise the Secretary to request information or documents in relation to all of those matters.

This item inserts a new regulation 8.1 into the Principal Regulations to prescribe a number of matters for the purposes of paragraph 41JA(1)(j) of the Act, such as whether the relevant devices are actually medical devices and whether the devices are correctly classified under Division 3.1 of Part 3 of the Principal Regulations.

These changes (taken together with the existing requirements of section 41JA of the Act) have the effect of allowing the Secretary to request information or documents from persons specified in paragraphs 41JA(1)(a) to (da) (including applicants for inclusion of a kind of device in the Register) about the full range of matters about which applicants for inclusion must certify under section 41FD of the Act, enabling the Secretary to determine if relevant regulatory requirements have been met.

Item [2] – Schedule 3A, clause 11

Clause 11 of Schedule 3A currently provides that if a person who has control over any unused emergency medical devices has not complied with a provision of Schedule 3A (which sets out

requirements in relation to the disposal of unused emergency medical devices for the purposes of section 41GY of the Act and regulation 6A.1), the Secretary may destroy the devices.

Emergency medical devices are medical devices exempted by the Minister under section 41GS of the Act from the requirement to be included in the Register in order for the devices to be stockpiled in order to create a preparedness to deal with a potential threat to public health that may be caused by a possible future emergency, or so as to make the devices available urgently in Australia to deal with an actual threat to public health caused by an emergency that has occurred.

When Schedule 3A, and other related provisions, were introduced to the Principal Regulations by the *Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No.3)* in October 2010, the Senate Standing Committee on Regulations and Ordinances recommended that clause 11 of Schedule 3A be amended to clarify that the intention in relation to that clause was that Secretary may order the destruction of unused emergency medical devices by a person other than the person who has control over the devices.

Item [2] therefore, amends the existing clause 11 of Schedule 3A to the Principal Regulations with the effect of making it clear that if a person who has control over any unused emergency has not complied with a provision of Schedule 3A, the Secretary may direct a person, other than the person who has control over the medical devices, to destroy the devices in the way directed.

Item [3] – Table of amendments – fees

This item increases the fee for an abridged conformity assessment, in paragraph 9.4(2)(b), by 3.4 per cent, subject to the TGA's rounding policy.

This item also increases the fees for all relevant items in Part 1 of Schedule 5, by 3.4 per cent, subject to the TGA's rounding policy.

Part 2 of Schedule 5 currently provides for additional fees for assessments that are required to be conducted outside Australia. These fees are currently calculated at a rate of $330 for each hour of preparation by each assessor involved.

This item also increases the hourly fee of $330 specified in paragraph 2.1(b) of Part 2 of Schedule 5, for preparation by an assessor conducting a review of compliance with conformity assessment certificate requirements or conformity assessment procedures outside Australia, by 3.4 per cent to $340.

These increases enable the TGA to recover its costs in administering the Act and to continue to meet the Government's Cost Recovery Guidelines.