

2010

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

THERAPEUTIC GOODS AMENDMENT (2010 MEASURES NO. 1) BILL 2010

EXPLANATORY MEMORANDUM

(Circulated by authority of the Hon Catherine King MP, Parliamentary Secretary for Health
and Ageing)

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OUTLINE

The Therapeutic Goods Amendment (2010 Measures No. 1) Bill 2010 (the Bill) makes a series of amendments to the *Therapeutic Goods Act 1989* (the Act). These include:

- a system for approving the supply of medical devices that are not on the Australian Register of Therapeutic Goods (the Register) to act as substitutes for devices that are on the Register but are unavailable or in short supply;
- a provision to allow listing on the Register of export-only variations of registered or listed medicines;
- amendments to provisions relating to permissible ingredients for inclusion in medicines;
- amendments relating to the information that may be considered by the Minister when reviewing initial decisions under the Act; and
- other minor amendments.

Schedule 1 – Exempting medical devices if substitutes are not widely available

At present section 19A of the Act allows the Secretary to approve the import and supply of medicines that can act as a substitute for medicines on the Register that are unavailable or in short supply. This provision is used to allow unapproved medicines to be obtained and supplied to cover transient shortages of approved medicines arising from manufacturing breakdowns or other supply chain problems. However, such a provision does not exist for medical devices. This Schedule inserts such a power in Chapter 4 of the Act, and makes a series of consequential amendments.

Schedule 2 – Other amendments

This Schedule makes a number of other amendments to the Act, including:

- allowing the Secretary to list export-only variations of medicines already included on the Register;
- modifying the system for the Minister to make lists of permitted ingredients for medicines;
- specifying the information that the Minister may consider in reviewing initial decisions under the Act; and
- clarifying the Secretary's information gathering powers in relation to medicines.

FINANCIAL IMPACT STATEMENT

The amendments made by this Bill will have a nil financial impact on the Commonwealth as the Therapeutic Goods Administration, which administers the Act, operates on a cost recovery basis.

THERAPEUTIC GOODS AMENDMENT (2010 MEASURES NO. 1) BILL 2010

NOTES ON CLAUSES

Clause 1: Short Title

Clause 1 is a formal provision specifying the short title of the Bill, once enacted, as the *Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010*.

Clause 2: Commencement

This clause provides that the Bill commences on Royal Assent and that the various Schedules commence as set out in the table.

Schedule 1 will commence the day after Royal Assent.

Part 1 of Schedule 2 will commence the 28th day after Royal Assent, to allow legislative instruments to be made under the amended provisions to come into force when the amendments to the Act take effect. Part 2 of the Schedule will commence the day after Royal Assent.

Clause 3: Schedules

This clause provides that each Act that is specified in a Schedule to this Bill is amended or repealed as set out in the relevant Schedule, and any other item in a Schedule to this Bill has effect in the way set out in the provision. The Bill makes amendments to the *Therapeutic Goods Act 1989* (the Act) and includes application provisions.

SCHEDULE 1 – Exempting medical devices if substitutes are not widely available

Therapeutic Goods Act 1989

Items 1 and 2

These items amend section 41H, setting out what is covered by Part 4-7 of the Act, to refer to the new exemption to be inserted as section 41HD by Item 3.

Item 3

This item inserts a new section 41HD at the end of Part 4-7.

Subsection (1) empowers the Secretary to provide an approval to a person to import, or import and supply, a specified medical device if the Secretary is satisfied that the kinds of medical devices included in the Register that could act as a substitute for the specified device are unavailable or in short supply, and

- the device is registered or approved for market access in at least one country specified in a determination under new subsection (5), or an application has been made under section 41FC to include a kind of device (which includes the device) in the Register;
- the device is specified in a determination under new subsection (6);
- the approval is necessary in the interests of public health.

Subsection (2) empowers the Secretary to provide an approval to a person to import, or import and supply, a specified medical device if the Secretary is satisfied that there are not any kinds of medical devices included in the Register that could act as a substitute for the specified device, and

- an application has been made under section 41FC to include the device in the Register;
- the device is specified in a determination under new subsection (6);
- the approval is necessary in the interests of public health.

Subsection (3) provides that an application for approval must be made to the Secretary and accompanied by any information required by the Secretary, and subsection (4) requires the Secretary, as soon as practicable after making a decision on the application, to inform the applicant of the decision, and the reasons for a negative decision.

Subsection (5) empowers the Secretary to make a legislative instrument specifying countries for the purpose of subsection (1), and subsection (6) empowers the Secretary to make a legislative instrument specifying the medical devices that can be the subject of an approval under this section.

Subsections (7) and (8) provide for the Secretary to impose conditions on an approval, and specify a period for the approval.

Subsections (9) and (10) deal with when an approval lapses. Under subsection (9) an approval lapses if the period specified in the approval expires, or a decision has been made on an application to include in the Register the kind of medical device that includes the device that is the subject of the approval. Subsection (10) provides that the approval lapses if the Secretary is satisfied that either the conditions that led to the approval no longer apply or that a condition of the approval has been contravened, and has notified the person to whom the approval was granted.

Subsection (11) explains that the lapsing of an approval through the expiry of time does not preclude another approval for the same device being granted before the expiry, to take effect on the expiry of the earlier approval.

Subsection (12) explains that an approval under subsection (1) or (2) is not a legislative instrument. This is because the approvals apply the law to a particular case, and do not create a general exemption.

Item 4

This item inserts a new section 41JFA into Part 4-8 of the Act, which deals with obtaining information about medical devices covered by exemptions from the Act. The new section relates to devices given an approval under new section 41HD (item 3 refers).

Subsection (1) provides for the Secretary to give a person who has been granted an approval under section 41HD a notice requiring the person to give the Secretary information or documents relating to the supply, handling, or monitoring of the device, the results of supply of the device, and any other matter prescribed by the regulations.

Subsection (2) provides that the notice must specify a reasonable period (of at least ten working days) for compliance, and subsection (3) provides that the notice may require information to be given in accordance with particular software requirements.

Items 5 to 9

These items make consequential amendments to sections 41JG, 41JH, 41JI and 41JJ, which establish criminal offences to failing to comply with a request for information under Part 4-7, or providing false or misleading information in response to a request, to include references to new section 41JFA (item 4 refers).

Items 10 to 15

These items make consequential amendments to section 41KA, dealing with the recall of medical devices in particular circumstances, to allow the recall of devices approved under section 41HD in those circumstances.

Items 16 to 20

These items make consequential amendments to section 41MI, which establishes criminal offences for importing, exporting, supplying or manufacturing devices which are not included in the Register, to provide that a person does not commit an offence if the device is one covered by an approval under section 41HD.

Item 21

This item makes a consequential amendment to section 41MIB, which allows imposition of a civil penalty for importing, exporting, supplying or manufacturing devices which are not included in the Register, to provide that a person does not contravene the section if the device is one covered by an approval under section 41HD.

Items 22 and 23

These items make consequential amendments to sections 41MK, establishing a criminal offence for wholesaling medical devices not included on the Register, to provide that a person does not commit an offence if the device is one covered by an approval under section 41HD.

Item 24

This item makes a consequential amendment to section 41MLA, which allows imposition of a civil penalty for making misrepresentations about medical devices, to include making a false or misleading representation that a device is one covered by an approval under section 41HD.

Item 25

This item makes a consequential amendment to subsection 41MN(9), which establishes a criminal offence for breaching a condition of an exemption from the Act for medical devices, to include a reference to a condition of approval under section 41HD.

Item 26

This item makes a consequential amendment to section 46A, which empowers authorised persons to search certain premises to monitor compliance with the Act, to extend it to the premises of a person who has been granted an approval under section 41HD.

Item 27

This item makes a consequential amendment to section 56A, which provides for the Secretary to provide evidentiary certificate of certain matters, to allow the Secretary to provide a certificate that there was no approval granted under section 41HD to a particular person in relation to particular devices.

Item 28

This item amends section 57, dealing with delegations, to add a new subsection (9) providing that the Secretary's powers under section 41HD may only be delegated to the National Manager of the Therapeutic Goods Administration (TGA) or officers of the TGA specified in the regulations. This is the same as existing subsection (8) relating to the powers of the Secretary under section 19A, which is the section on which section 41HD is based. No regulations have been made under subsection (8), and at this stage there is no intention to make regulations allowing delegation of the power under section 41HD.

SCHEDULE 2 – Other amendments

Part 1– Amendments commencing on the 28th day after Royal Assent

Therapeutic Goods Act 1989

Item 1

This item repeals paragraphs 26(1)(ea) and (eb), consequential on the re-enactment of section 26BB and the repeal of section 26BE made by items 3 and 5 respectively, and the insertion of new subsection 26(1AA) by item 9.

Item 2

This item replaces paragraphs 26A(2)(ca) to (cd) with new paragraphs (ca) and (cb). The effect of the amendment is that the persons applying to list medicines under the section must certify that the medicine:

- does not contain an ingredient that is not specified in a determination under paragraph 26BB(1)(a); or
- if a determination under paragraph 26BB(1)(b) specifies restrictions on the inclusion of ingredients in the medicine, none of the restrictions have been contravened.

Item 3

This item replaces section 26BB with a new section.

Subsection (1) empowers the Minister to make a legislative instrument specifying ingredients (paragraph (a)), and restrictions in relation to those ingredients being contained in medicines (paragraph (b)).

Subsection (2) provides that, the restrictions may relate to particular ingredients not been contained in particular medicine, and subsection (3) provides that the restrictions may relate to permitted concentrations or permitted total amounts of ingredients.

Subsection (4) provides that subsections (2) and (3) do not limit paragraph (1)(b).

Subsection (5) provides that a determination under paragraph (1)(b) may make different provision for different classes of medicine.

Subsection (6) empowers the Minister, by legislative instrument, to make a determination specifying ingredients that must not be specified under paragraph (1)(a). An equivalent power is contained in section 26BE, which is to be repealed (item 5 refers).

Subsection (7) provides that notwithstanding subsection 14(2) of the *Legislative Instruments Act 2003*, determinations made under this section may refer to other instruments or documents as in force from time to time.

The effect of these provisions is that the Minister may make a determination specifying, for example, that an ingredient may only be used in topical preparations at less than a particular concentration and cannot be used in other forms of medicine, or may be used in both topical and oral preparations but at different maximum concentrations.

Item 4

This item makes a consequential amendment to subsection 26BD(1) to refer to subsection 26BB(1) rather than section 26BB, following the amendment made by item 3.

Item 5

This item repeals section 26BE, as an equivalent power has now been included in section 26BB (item 3 refers).

Item 6

This item makes a consequential amendment to paragraph 30(1)(e) to remove references to paragraphs 26A(2)(cc) and (cd), which are to be repealed (item 2 refers).

Item 7

This item provides that the amendments made by items 1 and 2 apply to applications for listing made on or after the commencement of those items.

Part 2 – Amendments commencing on the day after Royal Assent

Therapeutic Goods Act 1989

Items 8 and 9

These items amend section 26 to provide an explicit path for the listing of export-only variants of medicines that are already included on the Register.

Item 8 amends subsection 26(1) to acknowledge that medicines may be listed in two ways under the section.

Item 9 inserts new subsections (1AA) and (1AB). Subsection (1AA) provides that the Secretary may list a new medicine in relation to a person if:

- an original medicine is included in the Register in relation to the person;
- the person applies under section 23 to list a new medicine;
- the Secretary is satisfied that the requirements of paragraphs 26(1)(a) to (ba) have been met;
- the Secretary is satisfied that the new medicine has the same characteristics as the original medicine, except characteristics specified in an instrument under subsection (1AB).

Subsection (1AB) empowers the Minister to make a legislative instrument specifying characteristics in respect of which the new medicine may differ from the original medicine. The Government intends that these characteristics will be colourings, flavourings, and excipients.

Items 10 and 11

These items amend subsection 31(1) which sets out matters in respect of which the Secretary may seek information from a person who has applied to register therapeutic goods or a person in relation to whom goods are registered.

Item 10 adds new paragraph (ga), allowing the Secretary to seek information relating to compliance with conditions of registration, and item 11 adds new paragraph (ha), allowing

the Secretary to seek information on whether the goods are being supplied, imported or exported. This information is important to ensuring compliance with the Act, and in assessing the extent of risk if problems with a medicine are detected.

Items 12 to 15

These items amend subsection 31(2) which sets out matters in respect of which the Secretary may seek information from a person who has applied to list therapeutic goods or a person in relation to whom goods are listed.

Item 12 adds new paragraph (ca), allowing the Secretary to seek information relating to the quality of the goods, and Item 13 amends paragraph (f) to allow the Secretary to seek information on the efficacy of the goods for the purposes for which they are to be used. Regulations made under paragraph 31(2)(h) already allow the Secretary to seek this information, and these powers are now being included in the Act for greater transparency.

Item 14 adds new paragraph (fa), allowing the Secretary to seek information relating to compliance with conditions of listing, and item 15 adds new paragraph (ga), allowing the Secretary to seek information on whether the goods are being supplied, imported or exported. This information is important in ensuring compliance with the Act, and in assessing the extent of risk if problems with a medicine are detected.

Item 16

This item amends paragraph 41EG(f) to provide that an application for a conformity assessment certificate lapses if the applicant fails to pay the fee in accordance with regulations made under Part 4-10 of the Act, dealing with payment of fees. The paragraph presently only requires payment after an applicant is notified of the decision on the application for a certificate. This had led to some applicants refusing to pay after been notified of an adverse decision, even though the TGA has incurred costs in conducting the audit of the application. While recovery action can be pursued in such cases, it is costly and may be ineffective.

Item 17

This item amends paragraph 41FK(e) to provide that an application to include a device in the Register lapses if the applicant fails to pay an assessment fee in accordance with sections 41LB and 41LC. The paragraph presently only requires payment after an applicant is notified of the decision on the application. This had led to some applicants refusing to pay after been notified of an adverse decision, even though the TGA has incurred costs in conducting the audit of the application. While recovery action can be pursued in such cases, it is costly and may be ineffective.

Items 18 to 20

These items amend section 60, dealing with reconsideration by the Minister of initial decisions under the Act made by the Secretary.

Item 18 adds a new subsection (2A) to provide that a request for reconsideration under subsection (2) may be accompanied by supporting information.

Item 19 adds a new subsection (3A) to provide that, subject to the requirements of subsection 60A(2) dealing with reconsideration of decisions relating to the registration of

therapeutic goods or the inclusion of medical devices in the Register, the Minister in reconsidering the decision, must

- take into account any information supplied under subsection (2A) by the person making the request (paragraph (a)); and
- must not take into account any other information supplied by or on behalf of the person after the request is made, other than information supplied in response to a request or information indicating that the quality, safety or efficacy of therapeutic goods is unacceptable (paragraph (b)).

The amendment at item 19 to prevent supporting information from being considered where it is provided after the request for reconsideration is made is necessary as such information is often complex and highly technical. As a result, it can require detailed consideration, assessment and analysis. This cannot readily occur where the Minister, or her or his delegate, is afforded less than the full 60 days in which to consider it. This is a particular problem in cases involving an initial decision on an application for registration, as the original information supplied in such cases often includes voluminous technical data and supporting information.

This item does not affect the 90 day period in which applicants may lodge a request for reconsideration of an initial decision.

Item 19 also adds a new subsection (3B) to provide that paragraph (3A)(a) does not limit the information the Minister may take into account.

Item 20 makes a technical amendment to subsection 60(4).

Item 21

This item sets out the application of various items in the Part.

Sub-item (1) provides that the amendment to subsection 26(1) made by item 8 and the new subsection 26(1AA) inserted by item 9 apply to applications for listing made on or after the commencement of that item.

Sub-item (2) provides that the amendments to section 31 made by items 10 to 15 apply in relation to requests for information made by the Secretary on or after the commencement of those items.

Sub-item (3) provides that the amendments to sections 41EG and 41FK made by items 16 and 17 apply to applications for conformity assessment certificates and inclusion in the Register made on or after the commencement of those items.

Sub-item (4) provides that the amendments to section 60 made by items 18 and 19 apply to initial decisions made on or after the commencement of those items.