Australian Government
Department of Health and Ageing

SECRETARY

Dr Ian Holland
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Dear Dr Holland

**Inquiry into the Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013**

Thank you for your letter of 5 April 2013 advising of the referral of the *Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013* to the Senate Community Affairs Legislation Committee for inquiry and report, and inviting the Department of Health and Ageing to provide a written submission to the Committee's inquiry.

Please find attached the Department's written submission to this inquiry.

Yours sincerely

Jane Halton PSM
Secretary

3 May 2013

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Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

# Submission to the Senate Community Affairs Legislation Committee

# Inquiry into the Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013

**3 May 2013**

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# 1. Introduction

On 20 March 2013 the Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013 (the Bill) was introduced into the House of Representatives. On 21 March 2013, the Senate referred the Bill to the Senate Community Affairs Legislation Committee for inquiry and report.

Appendix 18 of Selection of Bills Committee's Report No.4 of 2013 states that the Bill was referred to the Senate Community Affairs Legislation Committee for consideration of a number of technical amendments, specifically the changes set out in Schedules 3 (regarding goods that are not therapeutic goods) and 14 (regarding public notification and recovery of goods) of the Bill.

The Bill makes a series of minor and technical amendments designed to clarify the meaning, and streamline the operation, of a number of provisions in the *Therapeutic Goods Act 1989* (the Act). No new policy initiatives for the regulation of the different classes of therapeutic goods are included in the Bill.

Most of the amendments either address anomalies that have arisen as a result of amendments to the Act at different times over recent years, or have been designed to ensure, where appropriate, consistent regulatory treatment of the different types of therapeutic goods regulated under the Act, including prescription, over-the-counter and complementary medicines, biologicals and medical devices.

Many of the changes, including a new offence, have the effect of standardising or replicating a number of existing regulatory requirements to make more uniform or consistent some of the common processes, such as those relating to information gathering powers, that apply to all classes of therapeutic goods under the Act.

# 2. The operation of particular provisions in the Bill

### 2.1 Amendment of the definition of 'therapeutic goods' (Schedule 3 of the Bill)

An amendment has been included to enable the Minister, by way of a legislative instrument, to exclude goods from the scope of the regulatory scheme in the Act where, for example, it is clear that the goods in question have little to do with preventing or ameliorating illness or disease or have little connection with managing public health and safety but, because of therapeutic claims made, they come within the definition of 'therapeutic goods' in the Act. For example, the current definition is capable of capturing household items, jewellery and other products for which public health is not, or is unlikely to be, an issue.

Under the current definition, if therapeutic claims are made in relation to particular goods, they may potentially be subject to regulation under the Act, even if no public health risk is likely. Claims made about such goods may more appropriately be

regulated under consumer protection laws as false or misleading claims about goods, than the Act.

This new power will ensure that the focus of regulation under the Act remains directed at goods that have some impact on public health, and that the resources of the Therapeutic Goods Administration are more appropriately directed at the regulation of therapeutic goods and not household items, jewellery and a range of other goods in relation to which therapeutic claims may be made. The proper focus of regulation under the Act should be directed at products which could potentially represent a health risk to the Australian public.

Proposed section 7AA (see Schedule 3 of the Bill) will allow the Minister, by a disallowable instrument, to exclude such products from regulation under the Act, on a case-by-case basis because the definition of "therapeutic goods" will specifically exclude any such goods. Such exclusion would not prevent the excluded products from being regulated under other more appropriate laws.

The kind of matters that the Minister would take into account when considering whether to exclude products from regulation under the Act may include:

- whether the product is of a kind that has the potential to harm a person's health;
- whether the application of the regulatory requirements under the Act that are designed to test the safety, quality, efficacy and performance of a product for it to be supplied in Australia would be appropriate to a product of that kind; and
- whether the kinds of risks to which the public might be exposed from the supply of the product (for instance, unsupported therapeutic claims) can be more effectively managed under other Commonwealth or state and territory laws.

Determinations made by the Minister will take into account all relevant factors for the product in question and will be subject to parliamentary review through the disallowance process.

The new power is also intended to provide greater certainty and clarity for suppliers of products in relation to whether particular products are regulated under the Act. This is important because of the significant penalties for non-compliance with the Act. For instance, the Act provides significant criminal and civil penalties in the event that goods coming within the definition of "therapeutic goods" are imported, exported or supplied in Australia and are not included in the Register or not otherwise exempt from such inclusion.

The power to exclude particular goods from the definition of 'therapeutic goods' is quite separate from the existing powers under the Act to cancel goods from the Register about which there are safety, quality or efficacy issues. Such goods remain regulated under the Act as therapeutic goods.

The proposed power would not be used to exclude products such as prescription, over-the-counter and complementary medicines which are clearly appropriate for regulation under the Act.

## 2.2 Power to remove non-therapeutic goods from the Register (Schedule 3 of the Bill)

Only products that are 'therapeutic goods' are required to be regulated under the Act and included in Register. Proposed section 9F (see Schedule 3 of the Bill) would give the Secretary power to remove goods from the Register that do not fall within the definition of 'therapeutic goods' under the Act. Under the Act as it currently stands, there may be an argument that current cancellation powers under the Act only apply to 'therapeutic goods' and so cannot be used to remove goods in the Register that are not, or have ceased to be, therapeutic goods.

For example, under the Act a low risk medicine or medical device can be included in the Register electronically by a sponsor through listing without TGA scrutiny if the applicant/sponsor certifies as to a range of matters. It is only after the product has been included in the Register might it become apparent that the product is not in fact a therapeutic good as it does not satisfy the definition. Moreover, products that were therapeutic goods when included in the Register may cease to come within the definition where for instance, therapeutic claims are no longer made or (in the future) they come within a legislative instrument made by the Minister under proposed section 7AA.

The sponsor of goods proposed to be removed by the Secretary will have the opportunity to make submissions prior to any removal and will also have the right to internal and Administrative Appeals Tribunal review of any subsequent decision to remove the product from the Register.

The power to remove products from the Register is quite separate from the existing powers under the Act to cancel goods from the Register about which there are safety, quality or efficacy issues. Such goods do not stop being therapeutic goods and remain regulated under the Act as therapeutic goods.

## 2.3 Powers in relation to public notification and recovery (Schedule 14 of the Bill)

The powers of the Secretary in relation to therapeutic goods for which there may be safety or other regulatory issues have been strengthened. Apart from the existing power to order a recall of such goods in the circumstances set out in the legislation and to require sponsors to inform the public (or a specified class of persons) of those circumstances, under the amendments in Schedule 14 of the Bill, the Secretary will also be able to require the sponsor to provide additional information to the public, or a specified class of persons (e.g. particular patients or health care professionals), about the reasons for the suspension or cancellation of the goods from the Register, or the Secretary's conclusions about the safety, quality etc of the goods that could result, or has resulted, in a recall. In addition, the Secretary will also be able to require the sponsor to provide information about persons to whom the goods have been supplied.

As a result of these amendments, the Secretary will be able to more appropriately manage problem therapeutic goods by ensuring that the public, relevant health care

professionals and those who may have used the goods are more fully informed directly about those goods by the sponsor in a timely way.

Requiring the sponsor to supply information about persons to whom the goods have been supplied, to the Secretary will facilitate the ability of the TGA to take an active role in providing information directly to those persons in appropriate cases.

# 3. Summary of other main components of the Bill

## 3.1 Cancellation relating to presentation

Schedule 7 of the Bill contains an amendment to the Act which will provide a new ground for the Secretary to cancel therapeutic goods from the Register where they no longer meet regulatory requirements relating to 'presentation'. 'Presentation' means the way in which the goods are presented for supply, and includes matters relating to the name of the goods, the labelling and packaging of the goods and any advertising or other informational material associated with the goods.

Currently, the presentation of registered medicines and biologicals must be 'acceptable' to be included in the Register. The presentation of complementary and export - only medicines must not be 'unacceptable' to be included in the Register. What is 'unacceptable' presentation is defined in subsection 3(5) of the Act. The sponsor of a complementary medicine must certify, among other things, that the medicine's presentation is 'not unacceptable' before the goods can be listed in the Register. If the Secretary comes to a view that this was incorrect the Secretary can cancel the medicine from the Register.

The new power included in Schedule 7 of the Bill allows the Secretary to cancel goods from the Register as soon as presentation is not (i.e. no longer) acceptable (in the case of registered medicines and biologicals), or is unacceptable (in relation to complementary and export-only medicines). The effect will be that the requirements relating to presentation apply for so long as the goods remain on the Register. The purpose of the proposed new power is to ensure that those using a medicine are not misled about its use or characteristics or confuse it with other medicines after it has been included in the Register.

The Secretary can only cancel the goods after giving the sponsor the opportunity to make submissions, and the Secretary's decision to cancel will be subject to internal review and review by the Administrative Appeals Tribunal.

## 3.2 Cancellation relating to failure to provide information under section 31 of the Act

The Act contains a range of information gathering powers that the Secretary can use to inform herself when making a regulatory decision such as whether to include a product in the Register, whether to cancel or suspend a product from the Register, or whether to place conditions on a product in order to ensure compliance with regulatory requirements and standards. It is important that any regulatory decisions

made by the Secretary are fully informed by accurate information so as to ensure that powers are appropriately exercised.

Appropriate incentives will help ensure that sponsors respond in a timely way to requests from the Secretary for information. A major incentive is for the Secretary to have the power to cancel the registration or listing of therapeutic goods where the sponsor does not respond to a request for information within the (reasonable) timeframes set by the Secretary.

Currently, a power to cancel products from the Register where a sponsor has failed to provide information as requested about goods on the Register exists under section 31 of the Act but it is limited to requests for information about complementary medicines. To address this anomaly, amendments in Schedule 15 of the Bill extend the current cancellation power for a failure to provide information to cover all instances where a section 31 request for information is made (in relation to, for example, other classes of medicines and therapeutic devices) and the sponsor fails to provide the required information within the timeframe set by the Secretary.

This power is in line with the Secretary's existing powers in relation to requests for information about biologicals and medical devices.

The proposed power is important to underpin the integrity of the regulatory scheme - the section 31 request may relate to safety issues for a medicine currently in the Australian market about which it is critical that the Secretary is able to obtain information from the sponsor. While it is an offence to fail to comply with such a notice (subsection 31(4) of the Act), the ability for the Secretary to respond where vital information is not forthcoming by notifying of a proposal to cancel a product from the Register is essential to adequately protect public health and safety and fills a gap in the regulatory framework**.**

### 3.3. Offences

A new offence has been included in Schedule 11 of the Bill of providing false and misleading information in connection with an application under section 9D of the Act to vary information in the Register about a sponsor's products.

An amendment is also included in Schedule 2 to extend an existing offence in section 31 of the Act in relation to information gathering powers covering medicines and therapeutic devices to include all instances where a request for information has been made by the Secretary under that section.

#### 3.3.1. Schedule 11 of the Bill - Offences relating to section 9D variations

An offence has been included in the Bill where a sponsor provides information that is false or misleading in a material particular in connection with a request to vary information in the entry in the Register of a therapeutic good.

The Secretary relies on the information provided by the sponsor to decide whether to approve a request from a sponsor to make changes to a product that is on the Register. Such information can relate to whether the proposed change will either

have the effect of reducing the patient population for which the goods are approved (for instance by removing an indication for a medicine) or to demonstrate that the proposed change will not result in any reduction in the quality, safety or efficacy of the goods for the purposes for which they are to be used.

The provision of false or misleading information that was material to a decision of the Secretary to vary an entry in the Register could potentially have serious consequences for public health.

While it may be an offence under the Criminal Code to provide information that is false or misleading in a material particular in a request for such a variation, it is appropriate to include specific offence and civil penalty provisions in the Act that reflect the seriousness of the potential consequences.

The proposed provisions mirror the sanctions already in place in the Act for providing information that is false or misleading in a material particular in connection with an application for inclusion of therapeutic goods in the Register.

### 3.3.2. Schedule 2 of the Bill - Extension of existing offence for providing false or misleading information under section 31 of the Act

As noted above, the Act contains information gathering powers that the Secretary can use to support the making of a range of regulatory decisions and that it is important that any information that is provided in response to a request for information is accurate and correct, and not false or misleading in a material particular, so that decisions by the regulator are fully informed and appropriately exercised.

It is therefore appropriate that where information that is false or misleading in a material particular is provided to the Secretary, this should attract appropriate sanctions, by way or an offence or alternatively a civil penalty.

The Act contains offence and alternative civil penalty provisions for providing information that is false or misleading in a material particular in response to a request by the Secretary for information under section 31 about a listed medicine. The provisions currently do not however apply to information provided to the Secretary in response to a request for information about prescription medicines, over the counter medicines and export only medicines.

To address this anomaly, it is proposed that the current provisions be extended to cover all instances where a request for information is made under section 31 (in relation to, for example, other classes of medicines or therapeutic devices) and the sponsor provides information that is false or misleading in a material particular.

Such offence and civil penalty provisions already apply in relation to information provided in response to requests by the Secretary for information about biologicals and medical devices, but not currently to other therapeutic goods.

### 3.4 Other measures

The measures set out in Schedule 2 of the Bill are designed to put beyond doubt that in those instances where regulatory action in relation to therapeutic goods (such as decisions to include goods in the Register or to remove them from the Register, or decisions to seek more information to decide whether or not to include goods in the Register or to remove them from the Register) is predicated on whether or not the goods comply with applicable "advertising requirements", those requirements including compliance with the Therapeutic Goods Advertising Code made by the Minister under the Act, as well as any other applicable advertising requirement under the Act or Regulations.

The measures set out in Schedule 5 of the Bill are intended to clarify under which provision of the Act it is that the Secretary approves Product Information in relation to medicines (i.e. under section 25AA of the Act), and under which provision the Secretary decides whether or not to register a therapeutic good in the Register (i.e. under section 25 of the Act) following her evaluation of goods under section 25.

As the decision of the Secretary to approve Product Information is an integral part of the decision as to whether or not to register goods under section 25 of the Act, and underpins the registration decision under that section, the Bill provides that decisions made under section 25AA in relation to Product Information will not be the subject of a separate internal or AAT review.

The measures set out in Schedule 5 will also make it clear that where the Minister revokes an initial decision (of the Secretary) and makes a decision in substitution, the substituted decision is to be treated as a decision of the Secretary (except for any review of the substituted decision) to ensure that other administrative actions that need to be taken in order to make the decision effective (including registering the product) can be done.

The measures set out in Schedule 6 of the Bill amend section 28 of the Act to provide, principally, that where new conditions applying on the registration or listing of goods in the Register are imposed, or where a variation to an existing condition is made, and where this is at the request of the sponsor of those goods rather than by the Secretary, the conditions may commence earlier than the current period of 28 days after the date the sponsor is notified of the new or varied condition.

These measures will also enable the removal of an existing condition of registration or listing of goods in the Register to be effected earlier than the current 28 day period, if the sponsor requests the removal or if the Secretary decides to remove the condition in the absence of such a request. Schedule 6 also sets out equivalent amendments in relation to conditions relating to biologicals and medical devices.

These amendments will provide improved flexibility where there is a need for the quick implementation of a new condition, or variation or removal of an existing condition, where this is requested by the sponsor.

The measures set out in Schedule 12 amend subsection 30(5) of the Act to provide a minimum notice period (of at least 20 working days after the notice is given) before a cancellation of therapeutic goods from the Register in relation to which the Secretary is required to give notice, takes effect. It is an offence to supply therapeutic goods once they have been cancelled. This amendment ensures that the sponsor has time to take action to ensure it will not be committing an offence once the cancellation becomes effective and will bring the provision into alignment with the cancellation provisions for medical devices.

The measures set out in Schedule 13 of the Bill will give the Secretary the option of publishing information about various regulatory decisions made under the Act (including in relation to the suspension and cancellation of goods from the Register) on the Department's website rather than in the Gazette.

This will provide greater flexibility in the manner in which various decisions made under the Act may be communicated to the general public. Instead of publication in the Gazette, the Secretary will have the option of placing the information on the TGA website, to facilitate easier access to information by the public.

The measures set out in Schedule 16 of the Bill will strengthen the power of the Secretary to determine the kinds of information that must accompany an application to register or list goods in the Register. The Secretary may require any information that is specified in a legislative instrument made for that purpose.

It should be noted that the Bill does not contain measures implementing the TGA's Blueprint reforms on complementary medicines, medical devices and advertising. The TGA is currently consulting with stakeholders on potential reform options in these areas, but any such measures would be the subject of government consideration once the policy development process on those issues has been completed.