Australian Government

Department of Health and Ageing

ACTING SECRETARY

Dr Ian Holland
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Senate Standing Committees on Community Affairs
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Australia

Dear Dr Holland

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

Thank you for your letter to the Secretary of 15 May 2013 requesting responses from the Department of Health and Ageing to a number of questions posed by the Senate Community Affairs Legislation Committee in relation to its Inquiry into the *Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013*, and in relation to the issues outlined in the submissions to the Inquiry by Mr Doug Kentwell, and the Complementary Healthcare Council of Australia.

Please find attached the Department's written response addressing these matters.

Yours sincerely

Kerry Flanagan
Acting Secretary

27 May 2013

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Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Response to Issues Raised by the Senate Community Affairs Legislation Committee

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

28 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 (the Committee) for inquiry and report.

The Bill contains various amendments to the *Therapeutic Goods Act 1989* (the TG Act).

The Department of Health and Ageing (the Department) provided a written submission to the Committee's inquiry on 3 May 2013. The Department's submission has been made available on the Committee's website, as have other submissions.

The Committee has asked the Department to provide responses to a number of specific questions in relation to the Bill. In addition, the Committee has asked that the Department review and respond to the concerns outlined in the submissions from Mr Doug Kentwell (submission 7) and from the Complementary Healthcare Council of Australia (CHCA) (submission 8).

2. Response to the AMA's proposal relating to consumer protection

The Committee asked the Department to respond to the following:

> The AMA has recommended that consumer protection would be improved if "the Bill is amended to clarify that goods that are not 'therapeutic goods' for the purposes of the TG Act, are subject to Volume 3, Schedule 2, Part 4.1 of the CAC Act". Can the department respond to this proposal?

In its submission dated 2 May 2013, the Australian Medical Association (the AMA) recommended that the Bill be amended to make clear that any goods that are not 'therapeutic goods' for the purposes of the TG Act (by which the Department assumes is meant those goods that are taken out of the definition of 'therapeutic goods' by determinations of the Minister under proposed new section 7AA) are subject to Volume 3, Schedule 2, Part 4.1 of the *Competition and Consumer Act 2010* (the CCA).

The provisions in Volume 3, Schedule 2, Part 4.1 of the CCA (which are part of the Australian Consumer Law) are described as 'Offences relating to unfair practices' and include the section 151 offence of making false or misleading representations about goods.

Section 1 of Schedule 2 of the CCA, which sets out the Australian Consumer Law, states that Schedule 2 applies to the extent provided by Part XI of the CCA, or by an application law.

Relevantly, subsection 131(1) of Part XI of the CCA deals with the application of the ACL in relation to corporations, and notes that Schedule 2 (the ACL) "*applies as a law of the Commonwealth to the conduct of corporations, and in relation to contraventions of Chapter 2, 3 and 4 of Schedule 2 by corporations*".

It would not appear to be necessary to include an express provision in the TG Act in order for the relevant provisions in the CCA to apply to such goods. Goods that are specified as being excluded from the operation of the TG Act in a determination under proposed new section 7AA, or as being excluded goods when used, advertised or presented for supply in a specified way in a determination under proposed new section 7AA, would be subject to Schedule 2 of the CCA (or any particular part or provision of that Schedule) in any event.

This is because (as outlined above) under subsection 131(1) of the CCA, Schedule 2 of the CCA - i.e. the ACL - already applies (according to the terms of its provisions) to the actions of corporations.

This would include the offences set out in Chapter 4 of Schedule 2 of the CCA such as, for example, the offence at section 151 in relation to the making of a range of different kinds of false or misleading representations about goods or services in trade or commerce (e.g. that they are of a particular standard or quality), in connection with the supply or possible supply, or the promotion by any means of the supply or use, of goods or services.

This would also include a number of other important consumer protection provisions such as, for example, the prohibition at section 33 in Schedule 2 for a corporation (in trade or commerce) to engage in conduct that is liable to mislead the public as to the nature, manufacturing process, characteristics, suitability for purpose or quantity of any goods (whether therapeutic goods or not).

3. Outline of the consultation process prior to release of the Bill

The Committee asked the Department to respond to the following:

> Could the department outline the consultation process with industry and consumer stakeholders prior to the release of the Bill?

The Australian Dental Industry Association (the ADIA) in its submission dated 1 May 2013 expressed the view that as the amendments in the Bill are 'administrative in nature', any argument that it would not be appropriate to consult with industry and consumer stakeholders because of the sensitivities of the amendments would not have applied.

The Department notes the ADIA's comments in relation to lack of consultation. Consultation was not undertaken in relation to the Bill, as the amendments in it are principally designed to clarify the operation of a number of existing provisions in the TG Act, or ensure that various requirements in the TG Act are more consistent, and better aligned across the different types of therapeutic goods, rather than introducing new policy measures or implementing any of the reforms the Government is currently considering in relation to therapeutic goods.

There is extensive stakeholder and public consultation being undertaken in relation to the current reform proposals on medical devices and complementary medicines. There will also be consultation undertaken in relation to proposals relating to advertising reforms.

4. Explanation of the proposed change relating to the publication of regulatory decisions (aside from notice of removal)

The Committee has asked the Department to respond to the following:

> Can the department explain why the government believes that allowing the Secretary to publish regulatory decisions (aside from a notice of removal) in either the Australian Government Gazette or on the TGA website is consistent with transparency and good regulatory process?"

While the Australian Dental Industry Association (the ADIA) in its submission dated 1 May 2013 supports the publication of regulatory decisions on the TGA's website, '*in the interest of transparency and good regulatory process*', the ADIA considers that such decisions should also be featured in the *Australian Government Gazette*.

Publication on the TGA's website (noting that the TGA is a division of the Department of Health and Ageing) ensures maximum accessibility for consumers, industry health care professionals and the public to the information. There is also a cost to the TGA for publishing decisions in the *Gazette* (paid for by industry as the TGA operates on a 100% cost recovery basis).

Publication on the TGA's website is designed to provide the public with an easier, and more familiar, way of accessing information about regulatory decisions than through the *Gazette*. There is nothing to prevent the decisions being published in both, if that is considered appropriate.

5. Explanation of why allowing the Secretary to publish a notice of removal only on the TGA website is consistent with transparency and good regulatory process

The Committee has asked the Department to respond to the following:

> Can the department explain why the government believes that allowing the Secretary to publish a notice of removal (which has been effected under proposed section 9F) only on the TGA website is consistent with transparency and good regulatory process?

See the response to question 4 above.

6. Explanation of consultation requirements associated with decisions made under the Bill's provisions

The Committee has asked the Department to respond to the following:

> Medicines Australia have expressed concern about consultation requirements associated with decisions made under the bill's provisions. They note that there are consultation requirements associated with proposed section 9F, yet there is "no comparable requirement for an affected party to be consulted prior to the Minister declaring a good not to be a therapeutic good under a determination in 7AA(1) or (2)". Can the department explain why?

Medicines Australia noted in its submission dated 3 May 2013 that while the amendments are unlikely to affect its members, it seeks to ensure that industry members are properly consulted prior to industry interests being affected. Medicines Australia expressed concern in particular about the consultation that might precede an exercise by the Minister of the proposed new power in section 7AA to determine that products are not 'therapeutic goods'.

Consultation is likely to be undertaken before any exercise of the new power in proposed section 7AA, for example with sponsors and suppliers or products that are proposed to be excluded, as well as with consumer representative bodies. The *Legislative Instruments Act 2003* (the LI Act) sets out various requirements in relation to consultation requirements for legislative instruments. Unless a legislative instrument is, for instance, of a 'minor or machinery nature' that 'does not substantially alter existing arrangements' or is required as a 'matter of urgency' (section 18 of the LI Act refers), a rule-maker must not make a legislative instrument before being satisfied that any consultation that is considered by the rule-maker to be appropriate and reasonably practical to undertake has been undertaken (section 17 of the LI Act refers).

In addition, depending on the nature of any products proposed to be excluded, a Regulation Impact Statement (RIS) may also be required to be completed prior to the making of instruments under the new power as part of the Department's compliance with best practice regulation requirements.

7. Why 'unacceptable presentation' is defined in relation to listed products, but no definition of 'not acceptable' is proposed

The Committee has asked the Department to respond to the following:

> Why is 'unacceptable presentation' defined in relation to listed products, but no definition of 'not acceptable' is proposed?

Medicines Australia in its submission dated 3 May 2013 expressed concern about the proposed new power to suspend/cancel the registration of medicines on the grounds that their presentation

is 'not acceptable', given that the TG Act does not include a definition of the words 'not acceptable', and in light of uncertainty about the possible outcomes of the Labelling and Packaging review currently being undertaken by the TGA.

The Explanatory Memorandum (EM) for the Bill notes that in relation to the presentation of listed therapeutic goods being 'unacceptable', this is intended to refer to the meaning of that term as described in subsection 3(5) of the TG Act. This subsection states that presentation is unacceptable if it is capable of being misleading or confusing as to the content or proper use or identification of the goods, and sets out a number of additional circumstances where presentation will be unacceptable. These include, for example, where the label of goods does not declare the presence of therapeutically active ingredients, where a label suggests that the goods contain ingredients or have characteristics that they do not in fact contain or have, or if a form of presentation of the goods may lead to unsafe use of the goods or suggests a purpose that is not in accordance with the conditions applicable to the supply of the goods in Australia. 'Presentation' is defined in subsection 3(1) of the TG Act as the way in which goods are presented for supply and includes the name, labelling and packaging and any advertising or other informational material associated with the goods.

The EM also notes that "*In relation to registered goods, whether the presentation of such goods is 'not acceptable' can encompass a range of factors that might go beyond the scope of the definition of 'unacceptable presentation' in subsection 3(5) of the Act*".

This reference was not intended to imply that the matters set out in subsection 3(5) of the TG Act would not be relevant in considering whether the presentation of registered goods may be 'not acceptable'. Rather, this reference sets out that such matters *would* (where applicable) be relevant in understanding the meaning of 'not acceptable', but that there could also be other factors or circumstances (in addition to those in subsection 3(5)) in which the presentation of registered goods may not be acceptable. Such additional circumstances may relate to matters particular to registered medicines, such as the presentation of product information or consumer medicine information.

Medicines Australia has also requested the Committee to 'give greater consideration to this power, and its implications with the current Labelling and Packaging Review'.

The amendments in Schedule 7 of the Bill regarding presentation do not relate to, or pre-empt, the outcomes of the TGA's Labelling and Packaging Review, noting that the review process has not been completed, that consultations with stakeholders are still taking place and a Regulatory Impact Statement has yet to be finalised.

However, it is likely that the vehicle for any changes that might flow from the Labelling and Packaging Review would be a standard for relevant therapeutic goods made by the Minister (or a delegate of the Minister) under section 10 of the TG Act. Compliance with applicable standards is already a requirement under the TG Act for registered and listed goods (and goods for which registration or listing is sought) and failure to comply with such standards is a ground for suspension or cancellation of such goods from the Australian Therapeutic Goods Register (the Register). The proposed amendments in Schedule 7 are not related to such requirements – the amendments are concerned with compliance with presentation requirements rather than compliance with applicable standards.

Any changes to a standard arising out of the Labelling and Packaging Review would also be the subject of consultation before being made.

8. Outline of the potential impacts of the Labelling and Packaging Review on the criteria that may be used to deregister products whose presentation is 'not acceptable' and 'unacceptable'

The Committee has asked the Department to respond to the following:

> Can the Department outline the potential impacts of the Labelling and Packaging Review on the criteria that may be used to deregister products whose presentation is 'not acceptable' (in the case of registered products) and 'unacceptable' (in the case of listed products)?

If, as appears likely, the labelling and packaging reforms (which as noted above are yet to be finalised) are implemented through the making or amending of a standard for relevant therapeutic goods under section 10 of the TG Act, then it would be a breach of a standard if the sponsor of a product to which that standard applied did not comply with labelling requirements set out in that standard for the product.

As noted above, non-compliance with an applicable standard is already a grounds for cancellation or suspension of registered or listed therapeutic goods from the Register (paragraph 30(2)(e) of the TG Act refers), and the TG Act also contains equivalent requirements that goods the subject of an application for registration or listing comply with applicable standards. These requirements are separate to the grounds for cancellation or suspension from the Register, and to the requirements for registration or listing approval, relating to presentation.

It follows that the proposed new power would not be necessary for, or related to, the enforcing of any new labelling and packaging requirements as these are expected to be implemented using a different mechanism (compliance with applicable standards, as outlined above).

The purpose of the proposed power to cancel/suspend registered goods if their presentation is 'not acceptable' is to ensure that a pre-condition to the registration of a medicine in the Register (i.e. that its presentation is 'acceptable') operates as an ongoing requirement to be complied with for so long as the medicine remains on the Register.

If that were not to be the case, then the present situation would continue, whereby compliance with presentation requirements is only required at the point at which registration or listing is applied for but not at all times while the goods are on the Register, creates an anomaly. Such an outcome would not appear to be consistent with ensuring the safety of therapeutic goods available in Australia.

As noted above, any amendments to a standard arising out of the Labelling and Packaging Review will be the subject of consultation. The inclusion in the TG Act of the new power will not relate to, or compromise or pre-empt any decisions made about, the final content of the Review.

9. Response to concerns raised in the submission from Mr Doug Kentwell

The Committee has asked the Department to respond to the concerns raised in Mr Doug Kentwell's submission of 6 May 2013.

The issues raised by Mr Kentwell in relation to Schedules 5 and 9 are dealt with at 9.5 below.

9.1 Include reference to the need for the Act to be administered in accordance with human rights and freedoms

In his submission, Mr Kentwell refers to a case before the Administrative Appeals Tribunal that was unreported "as it was withdrawn by the sponsor", which involved an orphan drug. Mr Kentwell notes one of the grounds that the applicant advanced in that case was that "it was a fundamental human right to choose between an invasive versus non-invasive therapy", and that the respondent (the TGA), had responded in its Statement of Facts and Contentions "words to the effect that human rights had no place under the *Therapeutic Goods Act 1989*".

The Department has not been able to identify the matter described in Mr Kentwell's submission where the comments he alleges were made appear in the respective statement of facts and contentions.

Mr Kentwell has suggested that the TG Act be amended "to put beyond doubt that the Act [the TG Act] is administered in accordance with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*".

The *Human Rights (Parliamentary Scrutiny) Act 2011* deals with a quite specific obligation for members of Parliament and statutory rule-makers to provide a statement of compatibility with human rights to accompany Bills presented into a House of the Parliament and disallowable legislative instruments, and to ensure that such statements set out an assessment of whether the Bill or instrument is compatible with human rights as defined in section 3 of that Act. It does not deal with the extent to which other Commonwealth legislation is to be administered according to human rights, including the human rights covered by the instruments listed in section 3 of that Act.

A number of existing Commonwealth laws deal specifically with human rights and issues of discrimination, such as the *Racial Discrimination Act 1975,* the *Sex Discrimination Act 1984* and the *Disability Discrimination Act 1992*, and mechanisms are provided by which complaints about alleged breaches of the instruments referred to by Mr Kentwell can be pursued.

9.2 Advertising (Schedule 1)

Mr Kentwell is concerned that as the amendments included in Schedule 1 are aimed at 'ensuring reference to advertising includes a reference to the [Therapeutic Goods Advertising] Code' this will create uncertainty for industry because parts of the Code 'can be subject to very broad interpretation'. The Code 'therefore either needs substantial revision to eliminate doubt and uncertainty or the development of an annotated version to clearly guide the industry'.

The amendments in Schedule 1 in the Bill do not make any changes to the Therapeutic Goods Advertising Code (the Code), and are not 'substantive' changes. Apart from the proposed amendment to section 41GN described below, they do not add to the current powers of the Secretary relating to advertising requirements but rather are intended to make clear on the face of the legislation the meaning of the expression currently used to describe these requirements.

Under the TG Act, the following criterion underpins a number of regulatory requirements:

- "the goods conform to ... any requirements relating to advertising applicable under Part 5-1 [of the TG Act] or under the regulations..."

Consideration of this criterion is relevant to the following:

- it is one of the preconditions for the inclusion in the Register of different classes of therapeutic goods (medicines, biologicals, therapeutic /medical devices),
- it is one of the grounds on which the Secretary can require information or documents to be provided about medicines, biologicals or therapeutic /medical devices, and
- it is one of the grounds the Secretary must consider in determining whether to suspend or cancel medicines, biologicals or therapeutic/medical devices from the Register.

The effect of the amendments contained in Schedule 1 of the Bill is to make absolutely clear that the reference to "any requirements relating to advertising applicable under Part 5-1 [of the TG Act] or under the regulations" where it appears in the TG Act for these purposes includes a reference to the Code.

The proposed changes in Schedule 1 of the Bill therefore do not add to the current powers relating to advertising, but serve to put beyond doubt the existing requirements in relation to advertising requirements including the Code.

The one substantive amendment included in Schedule 1 is to section 41GN of the TG Act to include a power for the Secretary to cancel (after giving notice) a medical device from the Register for non-compliance with advertising requirements (including the Code). This brings the cancellation powers of the Secretary in relation to medical devices into line with her powers to cancel registered and listed therapeutic goods and biologicals from the Register for non-compliance with those requirements.

9.3 Goods that are not therapeutic goods (Schedule 3)

Mr Kentwell's concerns relate to both proposed section 7AA, where the necessity of such a provision is questioned in light of the existing section 7 of the TG Act, and proposed section 9F, in relation to which Mr Kentwell has raised three issues, which are addressed below.

Proposed section 7AA (Minister's power to determine product not a therapeutic good)

Section 7of the TG Act currently provides the Secretary with the administrative power to determine whether or not certain products are, or are not, therapeutic goods. The rationale behind this power is the recognition that there are numerous products where it may not be readily apparent whether they fall within the definition of 'therapeutic goods' in subsection 3(1) of the TG Act (particularly given the numerous exceptions contained in that definition (e.g., whether goods may be covered by a food standard made under the *Food Standards Australia New Zealand Act 1991*, or whether a product has a tradition of use as a 'food' in Australia or New Zealand)).

However, in order to exercise the administrative power, the Secretary must be satisfied that the product (in the case of a determination that a product is therapeutic goods) is in fact therapeutic goods, or (in the case of a determination that a product is not therapeutic goods) is not in fact therapeutic goods. The Secretary's decision is reviewable both by the Minister and by the Administrative Appeals Tribunal under section 60 of the TG Act.

The power of the Minister under proposed section 7AA, on the other hand, allows the Minister to declare a product (whether or not it comes within the definition of 'therapeutic goods' in the TG Act) not to be therapeutic goods, with the effect that the product so declared is no longer subject to regulation under the TG Act.

The primary reason for inserting this provision is to address the increasingly common practice for therapeutic claims to be made for a range of goods (perhaps to make them more appealing to health conscious consumers), even if they have no or little bearing on actually preventing, or alleviating any illness or injury, or any other health-related impact, with the result that these goods become subject to regulation under the TG Act.

The nature of the regulatory scheme under the TG Act may require scientific justification for therapeutic claims made about goods, and requires manufacturers of such goods to comply with manufacturing standards, as well as meet other standards such as international pharmacopoeias that determine what the profile of 'safe' therapeutic goods should be. It also requires products to be included in the Register before they can be imported, manufactured, supplied or advertised.

In general, as reflected in the Second Reading Speech, the Minister may exercise this power to respond flexibly, on a case-by-case basis, to ensure that products that are not suitable for regulation under the TG Act will not be regulated under that Act. As also noted in the speech, the kinds of matters that the Minister is likely to take into account when considering whether to exclude products from regulation under the TG Act by means of a determination under proposed section 7AA might 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 TG 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 apply 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 and/or state and territory laws.

Examples of goods that may well be inappropriate for regulation under the TG Act regulatory scheme include household items such as mattresses, and jewellery and clothing, for which therapeutic claims are made, and in relation to which none of the current exceptions to the definition of 'therapeutic goods' apply.

The new power cannot be used to expand the range of goods coming within the definition of 'therapeutic goods'.

Before the Minister exercises the power to make a legislative instrument, section 17 of the *Legislative Instruments Act 2003* requires appropriate consultation to be undertaken, and the instrument made is also subject to the parliamentary disallowance process.

Proposed section 7AA it is **not** an alternative mechanism to cancellation of goods from the Register. Cancellation of non-compliant therapeutic goods (e.g. on the basis that their safety or quality is unacceptable or that there has been a failure to comply with the advertising requirements applicable to the goods) does not take the cancelled therapeutic goods outside the regulatory regime. Therapeutic goods that are cancelled from the Register are still subject to regulation - the effect of cancellation is to make the importation, manufacture, supply and advertising of the product unlawful.

By way of contrast, a determination by the Minister under proposed section 7AA of the TG Act would not make the importation, manufacture, supply or advertising of the product unlawful under the TG Act. The product may well however be regulated under other Commonwealth legislation (for instance, if it is a food, it will be subject to any relevant standards made under the *Food Standards Australia New Zealand Act 1991* and enforceable under state and territory law) and be subject to the Australian Consumer Law.

The Minister would not use this power to take a therapeutic good that should be cancelled (for whatever reason) outside the regulatory regime.

To clarify, section 7 of the TG Act allows the Secretary to confirm by way of determination that goods are not therapeutic goods. It is predicated on the Secretary being satisfied that the goods are not in fact therapeutic goods. If there is insufficient material on which she could come to that view then no determination can be made. Section 7AA allows the Minister to declare that products are not therapeutic goods whether or not they come within the definition of therapeutic goods. The kinds of products in relation to which the Minister might make a determination would **not** be ones that in order to be supplied safely in Australia, require regulation of the kind found in the TG Act.

Proposed section 9F (Secretary's power to remove goods from the Register)

The issues Mr Kentwell raises in relation to the proposed power under section 9F of the TG Act to remove from the Register things that do not fall within the definition of 'therapeutic goods' are:

- there are no criteria upon which the Secretary is required to base a decision to remove a non-therapeutic product from the Register;

- the time limit within which the removal of a non-therapeutic good from the Register takes effect i.e. from the day the decision to remove is given to the person in relation to whom the goods are included in the Register; and
- any publication of the fact that a decision to remove a product from the Register under proposed section 9F should be required to be qualified in the event the product's status as a 'therapeutic good' is re-instated.

The reason for including proposed section 9F in the TG Act is to explicitly provide for situations where goods that are NOT therapeutic goods can be removed (not cancelled) from the Register.

There is an argument that the existing powers in the TG Act to cancel goods from the Register are predicated on goods being therapeutic goods (see, for example, the cancellation powers at sections 30, 32GC and 41GN of the TG Act). It could be argued that they are not available to be used by the Secretary in relation to products that for whatever reason, are on the Register but have never, or no longer, come within the definition of 'therapeutic goods' in subsection 3(1) of the TG Act. Goods which have never been therapeutic goods may be included on the Register as a result of listing by a sponsor through the Electronic Listing Facility (ELF) which allows certain kinds of low risk medicines (mainly complementary medicines) to be listed provided the sponsor certifies as to a range of matters and has paid the application fee. It is possible that products which are in fact certain kinds of 'food' (and excluded from the definition of 'therapeutic goods' in subsection 3(1) of the TG Act) may be included in the Register in this way.

Proposed section 9F therefore provides a separate power for the Secretary to address the situation where goods that do not fall within the description of 'therapeutic goods' in subsection 3(1) of the TG Act, or that have ceased to be a 'therapeutic goods' because one or more of the exceptions to the definition of 'therapeutic goods' apply, can be removed from the Register and therefore removed from regulation under the TG Act.

The sole 'criteria' for the exercise of the power in proposed section 9F would be that the Secretary is satisfied that the goods are not in fact 'therapeutic goods' within the meaning of subsection 3(1) of the TG Act.

In relation to Mr Kentwell's second point, unlike the situation where therapeutic goods are cancelled (in which case, as described above, the importation, manufacture, supply and advertising of the goods becomes unlawful), the removal of products from the Register on the basis they are not therapeutic goods results in no regulatory controls over the goods under the TG Act. For this reason it is not necessary to provide any time between the decision to remove the goods from the Register and the effective date of the decision.

This contrasts with a decision to cancel goods from the Register where the date of effect of the cancellation decision is usually 20 working days or 28 days minimum after the cancellation decision so as to allow the sponsor time to make arrangements to ensure it is not committing an offence under the TG Act by continuing to supply or advertise the product after that date.

In relation to Mr Kentwell's third point - that there is no obligation on the Secretary to ensure that particulars of the overturning of a decision to remove the product from the Register (for instance on internal review or by the Administrative Appeals Tribunal) is also published, the Department notes that there is no current obligation on the Secretary under the TG Act to publish in the *Gazette* outcomes of such reviews where the Secretary is obliged to publish particulars of the original decision in the *Gazette*. However, as part of the Blueprint reforms[1] currently being implemented, the TGA is considering the wider publication of information about its regulatory

[1] See http://www.tga.gov.au/about/tga-reforms-blueprint.htm.

decisions which would include providing information about the outcome of reviews of such decisions.

9.4 Restricted representations and prohibited representations (Schedule 4)

Mr Kentwell states that it is important that any conditions imposed by the Secretary (on the general use of prohibited or restricted representations) should not be inconsistent with the Therapeutic Goods Advertising Code (the Code).

Even if a condition imposed in relation to the use of a prohibited or restricted representation includes an obligation to include particular words, a delegate who is approving the use of the representation would takes steps to ensure consistency with the Code.

9.5 Rights of review in relation to the approval of Product Information (Schedules 5 and 9)

Mr Kentwell is concerned about the implications of the amendments in Schedule 5 of the Bill relating to the processes for approving the registration of medicines under section 25 of the TG Act and approval of Product Information for such medicines under section 25AA of the TG Act.

Schedule 5 of the Bill sets out amendments to the TG Act, principally to clarify the legal basis on which product information for a medicine is approved under the TG Act when a medicine is approved for registration or when the sponsor of a registered medicine seeks approval for a change to the approval for that medicine. The amendments put beyond doubt that it is section 25AA of the TG Act under which the product information is approved.

The amendments in Schedule 5 are also designed to make it clearer that:

- the Secretary of the Department of Health and Ageing (or her delegate) must, after having evaluated under subsection 25(1) of the TG Act therapeutic goods the subject of an application for registration, make a decision as to whether or not to accept the goods for registration (currently this is only implied in section 25 of the TG Act); and
- that the inclusion of the medicine in the Register following a decision to register the goods will only occur where a number of additional administrative steps have also been completed.

These administrative steps are the provision by an applicant for registration of the therapeutic goods of a certificate or notice to the Secretary as required under section 26B of the TG Act, and where the goods are required under the TG Act to have product information approved, the approval of product information under section 25AA of the TG Act for the goods. The steps are listed in proposed new section 25AAA in Schedule 5.

Product Information (PI) is a document that must be provided with particular kinds of medicines - mainly prescription and 'pharmacist only' medicines.

The PI sets out critical information about the medicine including the indication/s (i.e. what the medicine is to be used for), dosage and administration, composition, the medicine's contraindications (i.e. when the medicine must not be used) and any particular information and precautions concerning its use including its interactions with other medicines and adverse effects. It also contains information about the pharmacology and pharmacological actions of the medicine, clinical trials related to the indications, symptoms, signs and recommended treatment of overdose or accidental poisoning, presentation (dosage form, quantity, proportion or strength of each therapeutically active ingredient, container type, pack size etc) and storage conditions, the name and address of the sponsor and the relevant schedule of the Poisons Standard of the substance in the medicine.

The PI is for use by medical practitioners and others who prescribe medicines. The information it contains facilitates the proper and safe use of the medicine in patients with differing medical conditions. It is approved by the TGA as part of the approval process for the medicine.

A draft PI is provided by an applicant for registration of a relevant medicine and is considered by a delegate of the Secretary as part of the evaluation process under section 25 of the TG Act for that medicine. (Mr Kentwell is correct to say that the decision on PI is an integral part of the decision to register a prescription medicine in the Register.) Under that section, the Secretary must consider a range of matters when deciding whether to register a medicine including whether the quality, safety and efficacy of the medicine for the purpose for which it is to be used has been 'satisfactorily established'. A decision about the content of a PI is made under subsection 25AA(1) of the TG Act at the same time a decision is made to register the medicine.

A draft amended PI is also provided by the sponsor of a registered medicine requesting a variation under section 9D of the TG Act to the medicine's entry in the Register. The draft amended PI will be taken into account by the delegate in determining whether the variation should be approved under the section. In most cases, the variation can be approved either because the variation sought reduces the class of persons for whom the medicine is suitable or adds a warning or precaution (subsection 9D(2)) or because it does not otherwise indicate any reduction in the quality, safety or efficacy of the medicine (subsection 9D(3)). A decision about the content of the amended PI is made under subsection 25AA(4) of the TG Act at the same time a decision to vary the entry in the Register is made under the relevant subsection of section 9D of the TG Act.

As can be seen from a description of its contents, the PI essentially briefly describes and reflects various elements of the basis on which the decision that the safety, quality and efficacy of the medicine for the purpose for which it is to be used has been satisfactorily established so as to allow approval to be given for the medicine to be registered, or that approval to be varied at a later time.

Under section 60 of the TG Act a person whose 'interests are affected' by a decision under section 9D or under section 25 can seek merits review by the Minister of that decision and then by the Administrative Appeals Tribunal. This right to seek review is not limited to a decision to reject the application to register a medicine or not to approve a request to vary the entry of a registered medicine in the Register. It would also cover any aspect of a decision by the Secretary to register the medicine or to approve the variation.

Schedule 5 also amends section 60 of the TG Act to provide that a decision of the Secretary under section 25AA to approve product information will not be the subject of a right to internal merits review by the Minister or the Minister's delegate, or subsequently by the Administrative Appeals Tribunal (AAT).

Why the right to merits review was removed

As outlined in the Explanatory Memorandum to the Bill, the removal of a separate right to merits review for decisions by the Secretary to approve or vary product information under section 25AA principally reflects the fact that a decision to approve (or to vary existing) product information in relation to a medicine is an integral part of the corresponding decision of the Secretary in relation to whether or not to register the goods, or to agree to a variation of an existing entry in the Register for a medicine that has previously been approved.

There is also a concern that if the approval of product information were to be the subject of a separate right to merits review, a situation could arise whereby product information is altered through the merits review process and, as a result, contains information that is inconsistent with the basis upon which the goods were considered by the delegate of the Secretary to be suitable for registration including, in particular, in relation to its safety, quality and efficacy and/or does not accurately describe the basis on which the delegate came to the view that it could be safely prescribed or used for the purposes approved by the delegate.

In such circumstances, there would not appear to be a mechanism to amend or revisit the decision as to the registration of the medicine. Such an outcome could be confusing for prescribers, and could potentially pose a threat to the health of patients.

Whether there would be circumstances in which no merits review of a product information decision would be available

As outlined above, the Bill amends section 60 of the TG Act to remove a right to merits review of decisions relating to the approval of product information.

However, in practice, as described above, the product information is evaluated at the same time and as part of the evaluation of the application for registration of the medicine, or the request for a variation to an existing entry in the Register for a medicine that has already been approved is considered. The content of the product information is a critical element of the process by which the Secretary forms her view that the medicine can be registered on the basis that it satisfies the relevant statutory criteria or, as proposed to be varied, can continue to be registered.

The Secretary would not accept a medicine for registration (or make a variation to an existing medicine) unless satisfied that all the details in the product information properly reflected the exact basis on which the medicine was considered suitable for registration or continued registration.

As such, a right to merits review under section 60 in respect of the decision to register the medicine or to vary the Register entry in relation to the medicine will enable the addressing of any concerns that an applicant or sponsor may have with the product information approved as part of the registration or variation decision itself.

Subsection 25AA(4) of the TG Act, which authorises the Secretary to vary product information for medicines already in the Register following a section 9D request, also permits the Secretary to vary such product information where there is a change in conditions to which the inclusion of a medicine in the Register is subject which the Secretary is satisfied necessitates a change to the product information. In such circumstances, again, the relevant change to the product information would be taken into account as part of the decision-making process relating to the change of conditions, and a right to merits review in relation to the decision by the Secretary to impose or vary the condition would be available to the sponsor of the medicine under section 60.

With these points in mind, it is not considered that there would be any circumstances in which the merits review of a decision on registration, variation or the imposition or varying of a condition of registration which, because each such decision reflected and incorporated the delegate's views about the product information, would not also involve the review of any issues relating to the content of the product information (or changes to it).

9.6 The power to impose conditions of registration or listing (Schedule 6)

The amendments in Schedule 6 of the Bill cover two situations in relation to conditions applying to therapeutic goods in the Register:

- where a sponsor has requested the imposition of a new condition or a variation to an existing condition on therapeutic goods in the Register – the amendments will allow the Secretary's decision in relation to the request to come into effect earlier than 28 days/20 working days after the decision is made; and
- where a condition has been removed – the amendments will allow the Secretary's decision to remove the condition to come into effect earlier than 28 days/20 working days after the decision is made reflecting the fact that the removal of the condition is likely to result in a lessening of the regulatory load on the sponsor of the therapeutic goods.

There will be occasions where a sponsor may have requested new conditions, or variations to existing conditions, in order to accommodate business practices, or to address concerns about that sponsor's products in a more timely fashion to avoid any risk of their removal from the Register. In such circumstances a sponsor may seek to have conditions imposed or varied earlier than the current 28 days/20 working days when the new or varied conditions would normally come into

effect. This is considered to be of benefit to those sponsors, justifying an earlier implementation of the decision than is currently possible under the TG Act.

Mr Kentwell is concerned that the removal of a condition at the instigation of the Secretary (as opposed to the request of the sponsor) will not necessarily result in the lessening of the regulatory load so should not come into effect in less than 28 days/20 working days without the sponsor's agreement.

While given the nature of conditions imposed under the Act it is unlikely that removal of a condition will not result in a removal of a regulatory burden on the sponsor, it is possible. It should be noted that the amendments provide the Secretary with a discretion to specify a day earlier than 28 days/20 working days – it is not a requirement. In the rare case where removal of a condition does not result in the removal of a regulatory burden, this is a matter that the Secretary would no doubt take into account in specifying the day on which the condition is to come into effect taking into account its likely impact on the sponsor.

9.7 Presentation (Schedule 7)[2]

Mr Kentwell's concerns relate to the fact that what is not acceptable 'presentation' for higher risk therapeutic goods is not specified in detail in the TG Act, as is the case for the 'unacceptable presentation' of lower risk therapeutic goods under subsection 3(5) of the TG Act.

This reflects the current position under the TG Act, and the amendments in Schedule 7 do not make any changes to the existing requirements in relation to what constitutes 'unacceptable presentation' for lower risk products, or what would not be 'acceptable presentation' for higher risk products.

There has not been any description of what amounts to 'acceptable' presentation since the TG Act was first enacted. When evaluating higher risk medicines under section 25 of the TG Act there may be a wider range of issues, than what is currently provided for in subsection 3(5) of the TG Act, to consider for the purposes of determining whether the presentation of higher risk therapeutic goods would or would not be acceptable.

Any decision to not include medicines (section 25) or biologicals (section 32DG) in the Register because the presentation for those goods is not acceptable is subject to both internal review and review by the Administrative Appeals Tribunal under section 60 of the TG Act.

9.8 Publication of decisions on the website (Schedule 13)

Mr Kentwell is concerned about:

- the proposed requirement for the Secretary to publish information about the cancellation of any registered or listed therapeutic goods from the Register (proposed section 30B) does not also require the Secretary to publish information if that decision is later overturned; and
- the timeframe within which a person may apply for a review of a decision under section 60 of the TG Act.

<u>Publishing information about decisions to cancel</u>

The original version of the TG Act included a requirement (previously paragraph 30(6)(b) of the TG Act) that the Secretary publish in the *Gazette* particulars of all decisions to cancel the registration or listing of therapeutic goods from the Register. The provision was later omitted. Such a requirement however remains in relation to decisions to cancel biologicals from the Register (section 32GE) and to cancel medical devices from the Register (section 41GP). The

[2] This issue is also dealt with in the answer to question 7 above.

purpose of such a provision is to inform stakeholders who are either using cancelled products, or who have commercial dealings with cancelled products, about the regulatory status of those goods. In the event of a reversal of the cancellation of the goods, the goods would be re-instated in the Register and information about the cancellation then updated in the publicly available version of the Register on the TGA website.

With the exception of non-payment of annual charges or where a sponsor has requested cancellation, the grounds for cancellation normally revolve around the safety, efficacy or quality of therapeutic goods. Pending any decision to reverse a decision to cancel, the interests of public health and safety would appear to be better served by notifying stakeholders of the regulatory status of goods as soon as they are cancelled under section 30 of the TG Act. The inclusion of proposed section 30B brings listed and registered therapeutic goods back into line with the treatment of biologicals and medical devices.

Mr Kentwell is concerned in relation to the proposed inclusion of proposed section 30B that there is no obligation on the Secretary to ensure that particulars of any overturning of such a decision (for instance on internal review by the Minister or by the Administrative Appeals Tribunal under section 60 of the TG Act) is also published. The same argument is made in relation to the publication of decisions to cancel biological and medical devices.

As noted above[3], there is no current obligation on the Secretary under the TG Act to publish in the *Gazette* outcomes of such reviews but that as part of the Blueprint reforms currently being implemented, the TGA is considering the wider publication of information about its regulatory decisions which would include providing information about the outcome of reviews of such decisions.

Section 60 amendment

The proposed amendment of section 60 of the TG Act is intended to clarify the time limit within which an application for internal review can be lodged in relation to a decision that, under subsection 60(1), is subject to review by the Minister under that section.

Currently, any person whose 'interests are affected' by a decision can seek internal review under section 60 of the TG Act. Such persons will normally be the person in respect of whom the decision was made, for instance, the applicant for inclusion of a product in the Register or for a manufacturing licence or sponsor of a product cancelled from the Register. However, other persons may also be affected by decisions of the Secretary under the TG Act. If such a 'third party' can demonstrate that its 'interests are affected', it can seek review of that decision under section 60. In each case, the application for review must be made within 90 days.

Subsection 60(2) of the TG Act sets out the date from which the period of 90 days is to run. Currently the subsection provides that where the decision is of the kind particulars of which must, under the TG Act, be notified in the *Gazette* (for instance, decisions to cancel medical devices from the Register), the 90 days runs from when the particulars are included in the *Gazette*, and in any other case (i.e. where particulars of the decision are not required to be included in the *Gazette*) the 90 days runs from the day on which the decision comes to the notice of the person making the application for review.

As not all decisions are currently required to be notified in the *Gazette* (such as a decision to include a product in the Register), this can produce anomalous results in that for the person in respect of whom the decision is made, determining when the 90 days runs from does not depend on when the person was notified of the decision but the date on which the particulars were notified in the *Gazette*. In relation to third parties, it means that in the case of decisions

[3] Refer to heading 9.3 above,

particulars of which are not required to be published in the *Gazette*, the 90 days may not start running until months after the decision was made and came into effect.

The effect of the proposed amendment to subsection 60(2) of the TG Act is as follows:

- in relation to the person in respect of whom the decision is made and who is required to be notified of the decision by the Secretary (as is invariably the case under the TG Act) – the 90 days will run from when the notice is given to the person (the concept of 'given' is defined in section 28A of the *Acts Interpretation Act 1901*); and
- in any other case, (i.e. in relation to third parties) - the 90 days will run from the **earlier** of when the particulars of the decision is published in the *Gazette*/on the TGA's website, or the decision first comes to the person's notice.

This will provide greater certainty to the person in respect of whom the regulatory decision is made, and by tying the 90 day period to the publication of particulars of the decision in the *Gazette* or on the website, minimise the possibility that third parties seek to overturn many years later a decision in relation to which the sponsor will have acted in good faith, assuming the decision to be final.

Contrary to Mr Kentwell's submission, the 90 day period cannot be eroded as a result of late notification to a person who has a right to be notified of a decision under the TG Act. In such a case, the 90 days for that person will always run from when the notification was 'given', not when particulars may have been published on the website or in the *Gazette*.

Mr Kentwell also suggests that the reference to 'given' creates uncertainty in relation to the use of electronic communication mediums (such as email). The concept of 'given' is used extensively in the TG Act (see for instance sections 30, 31, 41JA, 32JA and 40B) in relation to the provision of notification by the Secretary and has not created the kind of uncertainty suggested by Mr Kentwell.

9.9 Cancellation where failure to comply with obligation to provide information (Schedule 15)

A power to cancel products from the Register where a sponsor has failed to provide information requested by the Secretary about listed and registered goods already exists under section 30 of the TG 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) but 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 made to sponsors for information about biologicals and medical devices where the sponsor has not complied.

The power is vital 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 TG 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.

Mr Kentwell is concerned that timeframes are not reasonable to get information from the (overseas) head or global offices of companies and that often extensions of time need to be sought by Australian sponsors because of unforeseen delays at head office.

The proposed amendment to subsection 30(2) of the TG Act specifies 14 days after the date nominated in the request as the period within which the sponsor must comply. The Secretary has complete discretion as to:

- the timeframe for the request itself (ie she could, for instance, specify 45 or 60 days, or a longer period, in the request);
- whether or not to exercise the proposed power to cancel the goods from the Register in the event of the request not being complied with.

Moreover, the exercise of the proposed power to cancel is predicated on the Secretary giving the sponsor notice of a proposal to cancel and the opportunity to make submissions in response (see subsection 30(3) of the TG Act) which the Secretary must take into account before making any final decision (see subsection 30(4) of the TG Act). Any cancellation decision is subject to internal review and review by the Administrative Appeals Tribunal (see section 60 of the TG Act).

9.10 Kind of information in s.23 and s.9D applications (Schedule 16)

Mr Kentwell has raised certain issues relating to the proposed amendments to sections 9D and 23 of the TG Act. In particular, Mr Kentwell states:

- that 'industry suspects' that finding a submission 'not effective' (with no merits review) is being used by the TGA to reject 'up front' any application that may ultimately be rejected under section 25, in order to avoid rights of review under section 60 that would otherwise apply to a rejected submission;
- the amendments have been prompted by the possibility of a legal challenge to the Streamlined Submission Process (and deeming applications to be ineffective under subsection 23(2) of the TG Act); and
- a right of review should be available to the applicant in relation to a finding by the TGA that an application is 'effective' under that subsection.

The issues dealing with applications not being "effective" are not the subject of the changes in Schedule 16.

The Streamlined Submission Process (SSP), which was developed by the TGA in close consultation with industry, is designed to respond to industry's wish that the TGA reduce the time within which evaluations of prescription medicines are completed. Before the SSP was implemented an evaluation of an application for registration of a prescription medicine could extend well beyond a year, often because not all the information required to complete the evaluation was provided by the applicant with the application submission. To achieve a reduced timeframe, it was agreed with industry that appropriate and adequate information must be lodged at the start of the process thus reducing the delays associated with the provision of additional information during the evaluation process itself. Under sections 9D and 25 of the TG Act, the Secretary can determine through the approval of a form, what information is required to be provided with the application 'as will allow the determination of the application'. If this information is not provided with the application, the application itself is taken not to be 'effective' under those sections and therefore cannot be evaluated.

The proposed amendments to sections 9D and 23 contained in Schedule 16 are intended to clarify the circumstances in which (and how) the Secretary approves the kind of information that must be provided for an application to be effective under those sections of the TG Act.

10. Response to concerns raised in the submission from the Complementary Healthcare Council of Australia

The Committee has asked the Department to respond to the concerns raised by the Complementary Healthcare Council of Australia (CHCA) in its submission.

10.1 section 7AA (Minister's power to determine a product is not a therapeutic good and thus take it out of regulation under the Act)

The CHCA is concerned that products that are in fact therapeutic goods may be excluded by means of a determination under proposed section 7AA, but no criteria for excluding goods by means of a determination made under the section has been included.

The Explanatory Memorandum for the Bill gives some examples of products that could be excluded, such as clothing, jewellery and household items. The Minister's Second Reading Speech describes the kind of criteria that the Minister is likely to take into account when considering whether to exclude products from regulation under the TG Act by means of a determination under proposed section 7AA as follows:

- 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.

The CHCA recommends limiting the power to products:

- where there is a 'severe or widespread consumer health safety concerns' that have no 'recognised therapeutic use'; or
- the ingredients of which are not in a section 26BB determination (i.e. permitted by the TG Act to be included in complementary medicines).

The purpose of the provision is not to exclude products from regulation under the TG Act that have a health safety concern or that contain ingredients that are not permitted to be included in complementary medicines. Indeed consideration would be given to cancelling such products from the Register so as to ensure that it would be unlawful to import, manufacture, supply or advertise them in Australia. As described elsewhere in this submission[4], the effect of proposed section 7AA is to enable the Minister to remove a product from regulation under the TG Act altogether on the basis that it is inherently unsuitable for regulation of the kind provided under the TG Act.

Any determination to remove products from regulation under the TG Act would be subject to appropriate consultation under section 17 of the *Legislative Instruments Act 2003* (which would require the Minister/Minister's delegate to undertake appropriate and reasonably practicable consultation where the legislative instrument is likely to have a direct or substantial indirect effect on business). The effect of removing products from the TG Act would be to remove all regulatory burden imposed under the TG Act.

As noted elsewhere in this submission[5], the removal of products from regulation under the TG Act however does not affect the operation of other Commonwealth legislation that also applies to those goods, such as the *Competition and Consumer Law Act 2010*, and in the case of products that

[4] Refer to heading 9.3 above.
[5] Refer to heading 2 above.

come within the definition of 'food' in the *Food Standards Australia New Zealand Act 1991*, subject to any relevant standard under that Act as well as regulation under relevant state and territory legislation.

10.2 section 9F (Secretary's power to remove products from the ARTG that are not therapeutic goods)

The CHCA is concerned that the Secretary will exercise powers under proposed section 9F to remove products from the Register based upon the outcome of the advertising complaints process established under the Therapeutic Goods Regulations. The CHCA also considers the proposed amendment is premature because the 'evidence guidelines' are still being considered and recommends that the Secretary should only be able to remove food products that are not and never have been therapeutic goods. It also argues that this power is already available to the Secretary under section 7 of the TG Act.

Proposed section 9F is not linked to outcomes of complaints about advertisements directed at therapeutic goods. The reason for including such a provision is to address the fact that the existing cancellation powers that permit the removal of goods from the Register under section 30 of the TG Act may be taken to be predicated on the goods in question being goods that come within the definition of 'therapeutic goods' in the TG Act. Section 9F is therefore appropriate to provide the Secretary with a clear power to remove from the Register goods that are **not** in fact therapeutic goods.

As mentioned elsewhere in this submission[6], the most likely use of the proposed power would be where a product has never been a therapeutic good (e.g. the product is excluded from the definition of 'therapeutic goods' in subsection 3(1) of the TG Act by reason that it comes within paragraph 3(1)(f) of that definition, i.e. it has a tradition of use in Australia and New Zealand as a food), or where therapeutic claims are no longer made in relation to the goods so the goods no longer come within paragraph (a) of the definition of 'therapeutic goods', or where a determination has been made by the Minister under proposed section 7AA in relation to the goods so they are no longer taken to be therapeutic goods under the TG Act.

Section 7 of the TG Act cannot be used, as suggested by CHCA, to remove products from the Register. Section 7 permits the Secretary to make administrative decisions to clarify whether or not, based upon the definition of 'therapeutic goods in subsection 3(1) of the TG Act, a product is or is not a therapeutic good but only where she is satisfied that the goods are otherwise therapeutic goods or not therapeutic goods, respectively. A determination by the Secretary under section 7 of the TG Act does not allow the Secretary to cancel any goods from the Register. The power to cancel goods in the Register is a separate power, (e.g. section 30 of the Act) and it could be argued, is predicated on the goods in question being therapeutic goods (and thus regulated under the TG Act), but non-compliant therapeutic goods. As noted elsewhere in the submission[7], cancellation of a product from the Register has the consequence that its importation, manufacture, supply or advertising becomes unlawful. The exercise of that power is also subject to both internal and external (i.e. Administrative Appeals Tribunal) review under section 60 of the TG Act.

10.3 presentation (Secretary's new power to suspend/cancel registered good on basis presentation 'not acceptable' and to cancel/suspend listed good on basis presentation 'unacceptable')

The CHCA is concerned that limitations in subsection 3(5) of the TG Act (which describes what amounts to 'unacceptable presentation') appear to have been removed (referring to the Minister's Second Reading Speech) and that the amendments proposed in Schedule 7 of the Bill are premature given that requirements for 'acceptable presentation' are 'currently under review'.

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[6] Refer to heading 9.3 above.
[7] Refer to heading 9.3 above.

It is assumed that CHCA is here referring to the current TGA review of labelling and packaging of therapeutic goods. As noted elsewhere in the submission[8], the review is still the subject of consultations with industry, and a Regulatory Impact Statement is in the process of being prepared.

The proposed amendments in Schedule 7 of the Bill relating to 'presentation' are not associated with the labelling and packaging review.

The 'presentation' of therapeutic goods is one of the considerations that is taken into account by the Secretary when deciding whether or not to include medicines in the Register. In the case of medicines that are required to be registered (higher risk medicines) section 25 of the TG Act provides that the Secretary must have regard to whether the 'presentation of the goods is acceptable'. In the case of complementary medicines, the Secretary is obliged to list them in the Register under section 26A of the TG Act if the sponsor of the goods has certified, amongst other things, that the 'the presentation of the medicine is not unacceptable'. As noted elsewhere in this submission[9], 'presentation' is defined in subsection 3(1) of the TG Act as the way in which goods are presented for supply and includes the name, labelling and packaging and any advertising or other informational material associated with the goods.

What is 'unacceptable' for this purpose is set out in subsection 3(5) of the TG Act. However, whether presentation for registrable goods is 'acceptable' is not defined in the TG Act, as the issues that are relevant in determining whether the presentation of higher risk medicines or biological is 'acceptable' or not may involve more than just the factors set out in subsection 3(5) of the TG Act, which applies in relation to the inclusion of lower risk medicines in the Register (see paragraph 26A(2)(c) of the TG Act which specifies that the applicant for the listing of a medicine under that section must certify that the presentation of the medicine is 'not unacceptable').

The distinction between 'unacceptable presentation' and 'acceptable presentation' is currently a feature of the Act, and the amendments contained in Schedule 7 do not change this. The purpose of the amendments set out in Schedule 7 is to ensure this distinction is preserved, so that for higher risk medicines and biologicals, the presentation of such goods must continue to be 'acceptable' for them to be included in the Register, whereas for lower risk products the presentation must not be 'unacceptable' within the meaning of subsection 3(5) of the TG Act to be eligible for listing in the Register.

The inclusion of a power to cancel goods from the Register on the basis of either presentation that is 'not acceptable' (for higher risk goods that are registrable goods) or 'unacceptable' (for lower risk goods that are listable goods) is to address an existing anomaly in the TG Act. While it is a precondition to the registration of higher risk goods that the Secretary is satisfied that presentation is 'acceptable' or that the applicant has certified that presentation of lower risk goods is 'not unacceptable', there is currently no corresponding mechanism for the Secretary to suspend or cancel such goods from the Register in the event that presentation is no longer 'acceptable' or no longer 'not unacceptable', respectively.

Including an express power for the Secretary to suspend or cancel goods from the Register on this basis will not compromise or prejudice any decisions made about the final content of the labelling and packaging standard. As noted elsewhere in this submission[10], the proposed labelling and packaging requirements being considered are proposed to be implemented by amendments to current standards made under section 10 of the TG Act. Non-compliance with such a standard is

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[8] Refer to heading 7 above.
[9] Refer to heading 7 above.
[10] Refer to headings 7 and 8 above.

already a ground for suspending or cancelling goods from the Register (see for instance paragraph 29D(1)(b) and paragraph 30(2)(e) of the TG Act). The cancellation powers proposed under Schedule 7 of the Bill will not impact any proposals that may emerge from the labelling and packaging review.

10. 4 advertising (changes to expressly refer to Advertising Code)

The CHCA is concerned that the amendments contained in Schedule 1 of the Bill are premature, given that advertising reforms proposed for therapeutic goods are under development. It also considers the amendments have the effect of 'broadening' the power to cancel products based on advertising without prior notification of the actual or anticipated impact - effectively a new power has been created without consultation with industry in anticipation of advertising reforms.

As noted elsewhere in this submission[11], the amendments to the TG Act in Schedule 1 of the Bill do not create a new power for the Secretary in relation to the inclusion of therapeutic goods in the Register, in seeking information or documents from applicants or sponsors or in suspending or cancelling therapeutic goods from the Register. The inclusion of the specific reference to the Therapeutic Goods Advertising Code where the expression 'requirements relating to advertising' is currently used in those provisions is to confirm that advertising requirements include those found in the Code as well as other provisions of the TG Act.

10. 5 Secretary's power to suspend/cancel (without notice) (s.30(1C)(b)) (page 13)

The CHCA is concerned that the proposed amendment to paragraph 30(1C)(b) of the TG Act extends the power of the Secretary to suspend or cancel listed goods (in this case complementary medicines) from the Register without notice.

Subsection 30(1C) of the TG Act currently allows the Secretary to cancel without notice a medicine listed under section 26A of the TG Act (mostly complementary medicines) if:

- the Secretary has requested information or documents from the sponsor of the medicine under section 31 of the TG Act 'for the purposes of ascertaining whether the medicine should have been listed'; and
- the sponsor has failed to comply within 20 working days after the request was made.

The only change to this provision made by item 1 in Schedule 2 of the Bill is to clarify what is meant by the expression 'whether the medicine should have been listed'.

10.6 Secretary's power to seek information about matters certified by applicant for listing (s.31(2)(fa)) (page 13)

The CHCA is concerned that this is a new power to delist a product (i.e. cancel a listed therapeutic good from the Register) if any of the certifications are incorrect.

Listed medicines are included on the Register via a low-cost and streamlined electronic application and validation process (ELF). At the time of listing it is the sponsor's responsibility to certify that its product complies with the requirements of the TG Act. If the sponsor certifies this on ELF, and the application fee has been paid, the medicine will be included on the Register. These certifications include that the product is eligible for listing i.e. it only includes certain ingredients the quality and safety of which have been considered by the TGA, that only low level claims are made in relation to the medicine, that the presentation of the medicine is not unacceptable, that the medicine complies with applicable standards and advertising requirements and that the sponsor holds evidence to support the claims made in relation to the product.

[11] Refer to heading 9.2 above.

The proposed new power will allow the Secretary to request information and documents from the sponsors of listed medicines about any of the certifications made by the sponsor at the time of the listing of a medicine in the Register, not just, as at present, the certification as to whether the sponsor holds evidence to support any claim made. This will provide the Secretary with material on which the Secretary can come to a view about whether the product complies with regulatory requirements in relation to the listing of the medicine.

The Secretary already has a power under paragraph 30(2)(ba) of the TG Act to suspend/cancel goods from the Register if it appears to her that certifications made at the time the goods were included in the Register are incorrect.

10.7 false or misleading statements (new offence in relation to information provided as part of s.9D request) (page 23)

The CHCA is concerned that 'there is a high degree of uncertainty confronting the complementary medicines industry, because of the incomplete raft of regulatory reforms', so it is 'premature' to make the proposed amendments (even though it supports the amendment in principle).

The proposed new offence is designed to ensure that information provided by a sponsor for the purpose of seeking the approval of a variation to the entry of its product in the Register is accurate and does not contain any information that is false or misleading in a material particular. It is essential that information provided by sponsors for their products can be relied upon by the regulator in making regulatory decisions in relation to that product. The offence provision mirrors provisions already included in the TG Act that apply to in relation to the making of applications for the inclusion of products in the Register or responding to requests from the Secretary for documents or information (see for instance, sections 22A and 22B, sections 41FE and 41FEA and sections 32DO and 32DP of the TG Act).

The proposed amendments are not related in any way to the regulatory reforms that are currently the subject of consultation with stakeholders or consideration by government.