
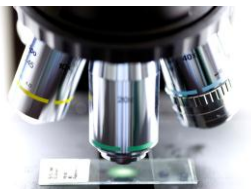


Complementary Healthcare Council of Australia

Response to the Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013 – A Bill for an Act to amend the Therapeutic Goods Act 1989, and for related purposes

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PREFACE

Complementary medicines and natural healthcare products are vitamins, minerals and nutritional supplements, special purpose foods, herbal and homeopathic medicines, aromatherapy products, and natural cosmetics using herbals and botanicals. Complementary medicines also comprise traditional medicines, including Traditional Chinese Medicines, Ayurvedic, and Australian Indigenous medicines.

Complementary medicines are generally available for use in self-selection by consumers and can be obtained from retail outlets such as pharmacies, supermarkets and health food stores. The majority of complementary medicines are indicated for the relief of symptoms of minor, self-limiting conditions, maintaining health and wellbeing, or the promotion or enhancement of health.[1]

The supply of complementary medicines and complementary healthcare products comprises an important and integral component of health care delivery to the community by providing an extensive range of products available for self-selection and for dispensing by healthcare professionals. Not surprisingly, half the adult population of Australia purchase a complementary medicine product at least every quarter.[2]

THE COMPLEMENTARY MEDICINES INDUSTRY PEAK BODY

The Complementary Healthcare Council of Australia (CHC) is the peak industry body for the complementary medicines industry. The CHC is unique in representing the entire supply chain from: manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors and retailers. The CHC is committed to a high growth and sustainable complementary medicines industry. We promote industry advancement, whilst ensuring consumers have access to complementary medicines of the highest quality, contributing to improved population health outcomes. We are the principal reference point for members, the government, the media and consumers to communicate about issues relating to the complementary medicine industry.

The CHC develops and manages a marketing code of conduct to which its members agree, and to which non-members are encouraged, to comply. This includes operating to the highest regulatory and ethical standards when sourcing, manufacturing and marketing complementary medicines.

THE COMPLEMENTARY MEDICINES INDUSTRY

The complementary medicines industry comprises entities that range in size from multinationals through to smaller regional-based business (typically SMEs). All industry stakeholders share a desire for complementary medicines to be an essential component of consumer healthcare.

Complementary medicine companies in Australia generate around $2 billion in annual revenues. In Australia the industry employs around 5,000 people in highly-skilled manufacturing jobs, and indirectly supports a further 60,000 jobs. The global market has been estimated at $US 83 billion annually[3].

Australian companies export around $200 million in complementary medicines to more than 20 countries in Southeast Asia, Europe and the America's, and continues to grow at higher rates than domestic consumption.[4]

1. Source TGA, http://www.tga.gov.au/industry/cm-basics-regulation-overview.htm
2. My Opinions Research, May 2011
3. The Australian National Audit Office, *Performance Audit Report No. 3 2011-2012*, Therapeutic Goods Regulation: Complementary Medicines, pp13.
4. CHC Industry Audit, May 2011.

CHC CONCERNS WITH THE INTERPRETATION AND APPLICATION OF THE BILL

The CHC agrees that *most* of the amendments are of a minor, technical nature, and has no comments or concerns in relation to these types of changes. However, some amendments are not minor or technical, but are new or broadened powers, and the CHC provides specific comments on some of these here.

> *The purpose of this bill is to make a number of minor but important changes … Most of the amendments are of a minor, technical nature, designed to ensure, where appropriate, consistent regulatory treatment of the different types of therapeutic goods including prescription, over-the-counter and complementary medicines, therapeutic devices, biologicals and medical devices.*[5]

The CHC agrees that the definition of 'therapeutic goods' in the Act is very broad and that work is required to amend, restrict or refine this definition.[6]

> *The definition of 'therapeutic goods' in subsection 3(1) has the potential, depending on how it is interpreted, to extend to a wide range of goods that may not have been intended to be regulated under the Act, including clothing and household items.*

In principle, amendment to the Act could assist in providing greater clarity around what is or is not a therapeutic good, however, the amendments proposed provide no clarity on the parameters of its application. The overall intent of this Amendment Bill appears to be transferring onus of proof of being a therapeutic good onto the supplier (sponsor) with recourse only through a Parliamentary process - without prior consultation or notification.

The biggest concern of the CHC is that the application of many of the measures in this Bill is premature.

Reasons:

1. The CHC believes that interpretation and application of the Therapeutic Goods Act 1989 has been changing and narrowing rapidly over the past five years – giving legal precedent for constant tightening of regulatory scope on vital areas, such as evidence, for what are essentially low risk products.
2. The regulatory reforms are on-going, particularly including Advertising and the *Evidence Required to Support Indications for Listed Medicines* Guidelines.

   Industry and the TGA are still in discussion to determine the required 'sufficient' levels of evidence in terms of: weight loss, clinical significance, biomarkers, bioavailability, nutrient supplementation, sources of established evidence; and therefore marketing claims.

   Industry and the TGA have not yet commenced discussion with regard to advertising.

CHC RECOMMENDATION

The CHC's strong recommendation is that the amendments proposed in Schedules 1, 2, 3, 7 and 11 not be applied until the current complementary medicine regulatory reform issues have been properly resolved.

5. The Hon Catherine King, MP, Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013, Second Reading Speech, para 3. Downloaded from: http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;db=CHAMBER;id=chamber%2Fhansardr%2F8143f75e-7f37-4128-8d3b-e62455d99a32%2F0086;query=Id%3A%22chamber%2Fhansardr%2F8143f75e-7f37-4128-8d3b-e62455d99a32%2F0000%22
6. Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013, Explanatory Memorandum, p. 1.

SUMMARY OF CONCERNS WITH REGARD TO NEW POWERS

MINISTER'S POWER

The CHC's concern is that there is no boundary to what the Minister can exclude from the Register and the definition of what may be excluded is incongruous.

> *The first [of the new measures] is to include a power for the Minister for Health to make a legislative instrument, the effect of which will be to exclude products from the definition of 'therapeutic goods' and thus remove them from regulation under the act.*[7]

> *The power for the Minister under new section 7AA of the Act will not require the Minister to come to a view that a product is not in fact therapeutic goods for it to be included in a determination.*[8]

Under the new power there is no defence against the removal of a product from the definition of a therapeutic good – if the decision can be made regardless of whether the Minister believes that a product is a therapeutic good or not.

While the CHC accepts that the examples given, in the Explanatory Memorandum and in the Parliamentary Secretary's Speech, may be more aptly dealt with under the Australian Consumer Law, there is the very real possibility that this could be used to include certain complementary medicines. For example: there are many products such as protein powders and medicinal honeys that may be considered to be borderline food-medicine products, albeit with legitimate therapeutic uses.

> *Some recent examples of goods for which therapeutic use claims have been made include mattresses which contain bacteria spores designed to reduce the effects of dust mites and 'power band' bracelets, which were claimed would boost a wearer's balance, strength and flexibility.*[9]

There are also some non-food therapeutic goods (homoeopathic medicines) that may be considered as more easily dealt with as non-therapeutic goods, notwithstanding that they are indeed therapeutic goods.

> *… 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.*[10]

Currently the Secretary may only exercise the powers under Section 7 to declare a product *not* a therapeutic good if satisfied that the product is not, in fact, a therapeutic good. Therefore, if genuine therapeutic products were to be excluded following the expansion of the Ministers powers, this would be an unintended consequence causing very real concern for the complementary medicines industry.

Section 7AA gives protection only to those goods under an order in force under a Section 7 Declaration. Therefore, all complementary medicines and devices used by complementary medicine healthcare professionals are eligible for exclusion by the Minister.

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7. The Hon Catherine King, MP, Ibid, para 5.
8. Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013, Explanatory Memorandum, p 22.
9. The Hon Catherine King, MP, Op Cit, para 5.
10. The Hon Catherine King, MP, Op Cit, para 6.

CHC Recommendation

The only situations where a Minister should be allowed to make a decision to exclude one or more complementary medicine products as therapeutic goods, should be in cases of:

(a) severe or widespread consumer health safety concerns from goods that have no recognised therapeutic use (appropriate powers are already in place in relation to therapeutic goods); or

(b) where the product's ingredients are not included under subsection 26BB of the Act, assuming the list of ingredients is appropriately maintained.

SECRETARY'S POWER

In Section 9F, new power is given to the Secretary to decide that a product is not, or is 'no longer' a therapeutic good.

> *This can come about, for instance, because sponsors of complementary medicines (emphasis added) and low-risk medical devices can list their goods in the register without pre-screening or assessment by the TGA using an electronic listing facility by certifying as to a range of matters about the goods.*[11]

The CHC agrees that the power to remove food products that are not, and have never been, therapeutic goods is appropriate, and this power already exists through application of a Section 7 declaration.

> *As a consequence there can be instances where products are on the register that are actually foods or that otherwise do not come within the definition of 'therapeutic goods'…*

However, the explanation goes on to state that:

> *… It is also possible that goods that were therapeutic goods when they were included in the register no longer come within the definition when claims of therapeutic use are no longer made (emphasis added).*

This broadens the power to an unacceptable extent to allow the Secretary to make a decision, solely on the basis of advertising claims - implicit in Section 9F. The removal of many claims of therapeutic use is based upon the decisions made through the complaints system. The CHC has concerns that the current process complaints system is fraught with inconsistency in decision making; the central complaints body acting outside the powers conferred to it by the legislation; and lack of an appropriate appeals mechanism.

Provision of this power is also premature in light of the fact that the regulatory reforms are on-going, particularly including Advertising and the *Evidence Required to Support Indications for Listed Medicines* Guidelines. Industry and the TGA are still in discussion to determine the required 'sufficient' levels of evidence in terms of: weight loss, clinical significance, biomarkers, bioavailability, nutrient supplementation, sources of established evidence; and therefore marketing claims. Industry and the TGA have not yet commenced discussion with regard to advertising.

There are no conceivable situations where a Secretary should be allowed to make a decision that a Listed (or Registered) complementary medicine product is no longer a therapeutic good.

CHC Recommendation

The Secretary should have the power only to remove food products that are not, and have never been, therapeutic goods. This power already exists through application of a Section 7 declaration.

11. The Hon Catherine King, MP, Op Cit, para 8

PRESENTATION

The current definition of unacceptable presentation is that in section 3(5) of the *Therapeutic Goods Act 1989*, and it is stated in the Explanatory Memorandum that this is the meaning given to unacceptable in paragraph 30(2)(aa)(ii).

However, the meaning of presentation given in the speech at the second reading appears to have been broadened and the limitations imposed by Section 3(5) appear to have been removed. The concern is that this is the interpretation that will be implemented.

> *A new ground for the secretary to suspend or cancel medicines from the register will be added to the act where its presentation no longer reaches an acceptable standard. … the presentation of medicines—which includes the name, labelling, packaging of the goods and any advertising or other informational material (emphasis added) associated with the goods …*[12]

Additionally, the requirements for the acceptable presentation of complementary medicines are currently under review and therefore it is inappropriate and premature to implement this new power.

Please refer also to **CHC Comments (7.1)**

Preferred Outcome

Confirmation and clarification that the current definition of unacceptable presentation is that prescribed under subsection 3(5) of the Act.
Until the requirements for 'acceptable presentation' are resolved, this new ground for cancellation should not be incorporated into the Act.

ADVERTISING

Underpinning the Therapeutic Goods Advertising Code directly in the Therapeutic Goods Act is premature at this time as the TGA's Advertising Reforms are yet to be finalised, current requirements are being made subject to new interpretations by Delegates but have yet to be formally notified to industry.

> *The amendments will make it clear that these advertising requirements include not only relevant advertising provisions in the act itself but also those contained in the therapeutic goods advertising code, which is made by the minister under the act.*[13]

Through this Amendment Bill, the ability of the Therapeutic Goods Administration (TGA) to cancel products based on advertising is being broadened, without any prior notification of the actual or anticipated impact. This is due to a lack of publicly shared information, at this point, with regard to the advertising reforms. Further information on this issue can be found in response to Schedule 1 amendments.

CHC Recommendation

The CHC is of the view that this broadening is effectively a new power, and there must be genuine and appropriate consultation with industry to ensure an efficient and cost effective advertising regulatory framework and an innovative and competitive industry BEFORE amendments to the underpinning Legislation are made.

12. The Hon Catherine King, MP, Op Cit, Para 10
13. The Hon Catherine King, MP, Op Cit, para 17

SCHEDULE 1—ADVERTISING

Item 1: Paragraph 25(1)(f)

Item 2: After paragraph 25(1)(f)

Item 3: Paragraph 26(1)(f)

Item 4: After paragraph 26(1)(f)

Item 5: Paragraph 26A(2)(d)

Item 6: After paragraph 26A(2)(d)

CHC COMMENTS (1.1)

Advertising Reforms

Underpinning the Therapeutic Goods Advertising Code directly in the Therapeutic Goods Act is premature at this time as the TGA's Advertising Reforms are yet to be finalised.

The TGA has advised that no further consultation on advertising will be undertaken prior to publication of a Regulatory Impact Statement. The reason given was that advertising consultation was extensive in the original ANZTPA process (abruptly stopped and not completed in 2007).[14]

In 2008, a brief update was given by the TGA and in 2010, a brief consultation was also held (focussed solely on identification of issues, rather than solutions). In May 2012, the *Advertising Regulatory Framework – Options for Reform report,* was published by the TGA, providing several options for change.

In January 2013, the Progress Report (as at 31 December 2012) for the *TGA Reforms: A blueprint for TGA's future* stated that upcoming outputs would include a set of refined options. These refined options are stated to be based on the May 2012 *Options for Reform* Paper – industry has not seen the refined options or been consulted as part of the upcoming Regulatory Impact Statement.

Through the Amendment Bill, the ability of the TGA to cancel products based on advertising is being broadened, without any prior notification of the actual or anticipated impact. This is due to a lack of publicly shared information at this point with regard to the advertising reforms.

The following outline some of industry's concerns that may or may not be addressed in the upcoming advertising reforms. [15]

14. It should be noted that the currently proposed ANZTPA environment is markedly different to the original ANZTPA environment. Complementary Medicines in New Zealand have been excluded from the proposed ANZTPA arrangements.
15. CHC Advertising Reform Position Statement, August 2009, http://www.chc.org.au/position-statements

Industry concerns with the existing regulatory framework for advertising:

- Difficulty in communicating bone fide news (due to lack of clarity regarding its definition)
- The inability to provide vital health information to consumers (ie: valid interactions with medical drugs and contraindications in specific diseases).

Industry concerns with the pre-approval system for advertising:

- The pre-approval system is complex and involves two different delegated authorities depending on the type of media in which the product is to be advertised;
- The use of different delegated authorities for different media for advertisements of the same product creates an environment conducive to inconsistency in decision making;
- There is no current provision of pre-evaluation assistance to advertisers or industry.

Industry concerns with the current process for handling of advertising complaints:

- Complaint handling for complementary medicines involves a number of different delegated authorities (CRC, CRP, ASMICP) and therefore has the clear potential for inconsistency in decision making;
- Time taken for handling complaints by some authorities can be two to six months (as per complaints decisions published on the CRP website), industry considers this to be too long;
- Complaints about the efficacy of a complementary medicine ingredient are being upheld, however these are considered to be more issues with the listing system than complaints about the advertising of a product per se;
- There is a lack of an appropriate appeal mechanism in order to have decisions of the Complaints Resolution Panel reviewed.

CHC and ASMI in 2012 formally established a joint Advertising Reference Group and commenced a process to inform an agreed industry position on definitions and substantiation of evidence criteria for marketing claims. The rationale for this was to provide sufficient guidance to industry (as agreed by industry) to minimise non-compliance with the Therapeutic Goods Advertising Code.[16] This document was submitted to the TGA in January 2013. No outcomes have yet been advised. Industry issues with pre-approval of advertisements and complaints are untenable and still exist – no clear guidance has been provided.

Complementary Medicines Regulatory Reforms

In addition, consultation is not yet complete with regard to the *TGA Blueprint: A blueprint for TGA's future* recommendations. Between now and December 2015 the TGA is expected to implement 44 Blueprint recommendations, of which 36 are likely to affect the complementary medicines industry. Most are significant projects with overlapping agendas, all of which require aligned implementation if they are not to be severely detrimental and costly to businesses.

Of particular note, the completion of the *Evidence Required to Support Indications for Listed Medicines* document, expected to be underpinned in the legislation, will impact on the acceptability of upcoming changes in the advertising framework to the complementary medicines industry. This *Evidence Required to Support Indication for Listed Medicines* document incorporates sources of established evidence, weight loss, biomarkers, nutrient supplementation & clinical significance. Parallel to this consultation is the Permitted (Coded) Indications for Listed Medicines project, and the Labelling and Packaging review.

16. CHC Issues Paper on the Substantiation of Claims to Comply with the Therapeutic Goods Advertising Code, January 2013, http://www.chc.org.au/Submissions

Item 7: Paragraph 30(1A)(c)

Item 8: Paragraph 30(2)(ba)

Item 9: Paragraph 30(2)(e)

Item 10: After paragraph 30(2)(e)

CHC COMMENTS (1.2)

Cancellation *without notice* for non-compliance with advertising requirements causes the industry grave concern.[17]

This concern is exacerbated by:

(1) the same comments as presented above, please refer to **CHC Comments (1.1)**;

(2) inability of the Complaints Resolution Panel, established under the *Therapeutic Goods Regulations 1990* 42R, to operate within its limits;

(3) insufficient complementary medicine understanding on the Complaints Resolution Panel;

(4) decision making processes within the Complaints Resolution Panel are inherently biased against complementary medicines;

(5) permitted current abuse of this complaints system by individuals;

(6) current use of the media by (complementary medicine) industry critics to publicly condemn the TGA appears to be unfairly driving and influencing its decisions; and

(7) the fact that Paragraph 30(1A)(c) already confers the power to cancel the registration or listing of a product where *the breach is significant and as a result of the breach, the presentation of the medicine is misleading to a significant extent* - amending the provisions will not improve or strengthen the powers already in place.

Item 11: After paragraph 31(1)(ga)

Item 12: Paragraph 31(1)(h)

Item 13: Paragraph 31(2)(g)

Item 14: After paragraph 31(2)(g)

CHC COMMENTS (1.3)

These comments are also applicable in relation to non-invasive medical devices used by complementary medicine healthcare professionals.
The same comments apply as presented above, please refer to **CHC Comments (1.1)**.
This schedule will have consequences for devices used by complementary medicine healthcare professionals.

17. Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013, Explanatory Memorandum, pp. 8-9.

Item 15: Paragraph 32DA(3)(d)

Item 16: Paragraph 32DE(1)(d)

Item 17: Paragraph 32GA(1)(j)

Item 18: Paragraph 32GC(1)(g)

Item 19: Paragraph 32JA(1)(m)

Biologicals, the CHC has no comment.

Item 20: Paragraph 41FD(h)

Item 21: Paragraph 41GL(h)

Item 22: At the end of subsection 41GN(1) (before the note)

Item 23: Paragraph 41JA(1)(h)

CHC COMMENTS (1.4)

These comments are in relation to non-invasive medical devices used by complementary medicine healthcare professionals.
The same comments apply, as presented above, please refer to **CHC Comments (1.1)**.
This Schedule will have consequences for devices used by complementary medicine healthcare professionals.

Item 24: Application—medicines etc.

CHC COMMENTS (1.5)

24 (1-6): Given that the CHC believes that amendments to Sections 25, 26, 26A, 31, and subsections 30(1A), 30(2) should not be approved prior to finalisation of the Blueprint and ANZTPA reforms, this item should not be commenced.

24 (4-6): The CHC does not support that the amendments to subsections 30(1A) and 30(2) and section 31 should be applied to breaches that occur prior to commencement. That is, new powers should not be applied retrospectively.

Item 25: Application—biologicals

Biologicals, the CHC has no comment.

Item 26: Application—medical devices

CHC COMMENTS (1.6)

These comments are in relation to non-invasive medical devices used by complementary medicine healthcare professionals.

26 (1-4): Given that the CHC believes the sections 41FD, 41GL, subsections 41GN (1), 41JA(1) should not be approved prior to finalisation of the Blueprint and ANZTPA reforms, this item should not be commenced.

24 (2-4): The CHC does not support that the amendments to sections 41FD, 41GL, subsections 41GN(1), 41JA(1) should be applied to breaches that occur prior to commencement.

SCHEDULE 2—OBTAINING INFORMATION ETC.

Item 1: Paragraph 30(1C)(b)

CHC COMMENTS (2.1)

The current power under subsection 30(1C)(b) allows a product to be removed from the register if it is believed the medicine should never have been listed. The new power appears to be that a product can be delisted if any one of the certifications (safety, presentation, conforming to all applicable standards) is incorrect.

Decisions in regards to adequacy of evidence to support indications and claims are being made subject to new interpretations by Delegates but have yet to be formally notified to industry. Therefore the broadening of this power is premature.

Item 2: Section 31 (at the end of the heading)

The CHC has no concerns with the amendments in this Item, at this time.

Item 3: Paragraph 31(2)(fa)

CHC COMMENTS (2.2)

The new power under subsection 31(2)(fa) appears to be that a product can be delisted if any one of the certifications (safety, presentation, conforming to all applicable standards) is incorrect.

Decisions in regards to adequacy of evidence to support indications and claims are being made subject to new interpretations by Delegates but have yet to be formally notified to industry. Therefore the broadening of this power is premature.

Item 4: Paragraphs 31(5A)(a) to (c)

Item 5: Subparagraphs 31(5A)(d)(i) and (ii)

Item 6: Paragraphs 31(5B)(a) to (c)

Item 7: Paragraph 31(5B)(d)

Item 8: Subsection 31(6)

Item 9: Section 31AAA (heading)

Item 10: Paragraphs 31AAA(a) and (b)

Item 11: Paragraph 31AAA(c)

The CHC has no concerns with the amendments in these Items, at this time.

Item 12: Paragraph 32GB(1)(b)

Item 13: After paragraph 32JA(1)(j)

Item 14: Paragraph 32JB(1)(a)

Biologicals, the CHC has no comment.

Item 15: Paragraph 41GM(1)(b)

Item 16: Section 41JA (at the end of the heading)

Item 17: After paragraph 41JA(1)(ib)

Item 18: Paragraph 41JB(3)(a)

Devices, the CHC has no comment

Item 19: Application of amendments

CHC COMMENTS (2.3)

The CHC has concerns with the premature application of this Schedule.

SCHEDULE 3—GOODS THAT ARE NOT THERAPEUTIC GOODS

Item 1: Subsection 3(1) (at the end of the definition of therapeutic goods)

Item 2: After section 7

Item 3: At the end of paragraph 8(1)(b)

Item 4: After paragraph 8(1)(b)

CHC COMMENTS (3.1)

In this amendment, the Minister appears to have been given unfettered power to make determinations: "The power for the Minister under new section 7AA of the Act will not require the Minister to come to a view that a product is not in fact a therapeutic good for it to be included in a determination."[18]

The clauses in Section 7AA give protection only to those goods under an order in force under a Section 7. Therefore *all* complementary medicines and devices used by complementary medicine healthcare professionals are eligible for exclusion by the Minister.

The only situations where a Minister should be allowed to make a decision to exclude one or more complementary medicine products as therapeutic goods, should be in cases of:

(a) severe or widespread consumer health safety concerns from goods that have no recognised therapeutic use (appropriate powers are already in place in relation to therapeutic goods); or

(b) where the product's ingredients are not included under subsection 26BB of the Act, assuming the list of ingredients is appropriately maintained.

Please also refer to the discussion under the Heading 'Minister's Power' in this document.

Item 5: At the end of Chapter 2

Item 6: After paragraph 56A(1)(h)

Item 7: Subsection 60(1) (paragraph (ab) of the definition of initial decision)

CHC COMMENTS (3.2)

In Section 9F, power is given to the Secretary to decide that a product is 'no longer' a therapeutic good, solely on the basis of advertising claims, in addition to other causes for removal. Provision of this power is premature in light of the fact that the regulatory reforms are on-going, including advertising and levels of evidence guidance.

The Secretary should have the power only to remove food products that are not, and have never been, therapeutic goods. This power already exists through application of a Section 7 declaration.

Please also refer to the discussion under the Heading 'Secretary's Power' in this document.

Item 8: Application—removal of entries from Register

CHC COMMENTS (3.3)

The CHC has concerns with the premature application of this Schedule.

18. Ibid, p. 22.

SCHEDULE 4—RESTRICTED REPRESENTATIONS AND PROHIBITED REPRESENTATIONS

Item 1: At the end of section 42DK

Item 2: Paragraph 42DL(1)(a)

Item 3: Before paragraph 42DL(2)(a)

Item 4: Paragraph 42DL(3)(a)

Item 5: Application of amendments

The CHC has no concerns with the amendments in this Schedule, at this time.

SCHEDULE 5—EVALUATION AND REGISTRATION OF THERAPEUTIC GOODS

Item 1: Paragraph 19A(8)(b)

Item 2: Subsection 24D(3)

Item 3: Section 25 (heading)

Item 4: Subsections 25(3), (4) and (5)

Item 5: After section 25

Item 6: Subsection 25AA(1)

Item 7: Paragraphs 25AA(2)(b) and (3)(b)

Item 8: Paragraph 25AA(3)(c)

Item 9: Section 26BA

Item 10: Subsection 60(1) (paragraph (c) of the definition of initial decision)

Item 11: Application of amendments

The CHC has no concerns with the amendments in this Schedule, at this time.

SCHEDULE 6—CONDITIONS OF REGISTRATION OR LISTING

Item 1: After paragraph 28(4)(a)

Item 2: Paragraph 28(5)(e)

Item 3: After paragraph 32EE(3)(a)

Item 4: Subsection 41EL(2)

Item 5: After paragraph 41EL(2)(a)

Item 6: Subsection 41FP(2)

Item 7: After paragraph 41FP(2)(a)

Item 8: Application of amendments

The CHC has no concerns with the amendments in this Schedule, at this time.

SCHEDULE 7—PRESENTATION

Item 1: After paragraph 30(2)(a)

Item 2: Subsection 30EA(1) (cell at table item 5A, column headed "Circumstance relating to therapeutic goods")

Item 3: Paragraph 32GC(1)(a)

Item 4: Subsection 32HA(1) (table item 9)

CHC COMMENTS (7.1)

The current definition of unacceptable presentation is that in section 3(5) of the *Therapeutic Goods Act 1989*, and it is stated in the Explanatory Memorandum that this is the meaning given to unacceptable in paragraph 30(2)(aa)(ii).

The TGA has implemented new interpretations of evidence requirements that are informing proposed amendments to the *Evidence Required to Support Indications for Listed Medicines* Guidelines that render meeting the definition of 'not acceptable' impossible for many complementary medicine products.

The TGA has also implemented new interpretations of the *Therapeutic Goods Advertising Code 2007* that rely on the new interpretation of the evidence requirements. This has already impacted on advertising pre-approvals.

It is inappropriate and premature to implement this new power, particularly because:

(a) the reforms as described in **CHC Comments (1.1)** are still not finalised.

(b) the consultation documents (for example: levels of evidence; labelling & packaging; permissible indications; and advertising) that have been put to industry for consultation make meeting the definition of 'not acceptable' impossible for many complementary medicine products.

Please also refer to the discussion under the Heading 'Secretary's Power' in this document and **CHC Comments (1.1)** and **(1.2)**.

Item 5: Application of amendments

CHC COMMENTS (7.2)

The parameters of the definition of 'presentation' are a moving target and therefore the application of these amendments should be viewed as premature.

SCHEDULE 8—CONSENT TO THE IMPORT, SUPPLY OR EXPORT OF GOODS

Item 1 Subsection 60(1) (paragraph (b) of the definition of initial decision)

Item 2 Application of amendment

The CHC has no concerns with the amendments in this Schedule, at this time.

SCHEDULE 9—REVIEW OF DECISIONS

Item 1 After subsection 60(3B)

Item 2 Application of amendment

The CHC has no concerns with the amendments in this Schedule, at this time.

SCHEDULE 10—KITS

Item 1 Subsection 7B(1)

Item 2 Application of amendment

CHC COMMENTS (10.1)

If the limit of this amendment is to define a kit as a package that now needs to include at least one therapeutic good, rather than the previous requirement for a minimum of two separate therapeutic goods, then this is acceptable.

SCHEDULE 11—FALSE OR MISLEADING STATEMENTS

Item 1 Before Chapter 3

Item 2 Section 53A (before table item 1)

CHC COMMENTS (11.1)

The amendments in this schedule are supported in principle.

There is a high degree of uncertainty confronting the complementary medicines industry, because of the incomplete raft of regulatory reforms.

Please also refer to:

- the discussion under the Headings 'CHC Concerns with the Interpretation and Application of the Bill' and 'Summary of CHC Concerns with Regard to New Powers'; and
- **CHC Comments (1.1)**.

Item 3 Application of amendments

CHC COMMENTS (11.2)

The parameters of the definition of 'misleading statements' are a moving target and therefore the application of criminal offences should be viewed as premature.

SCHEDULE 12—NOTICE OF CANCELLATION OF REGISTRATION OR LISTING

Item 1 Paragraph 30(5)(b)

Item 2 Application of amendment

The CHC has no concerns with the amendments in this Schedule, at this time.

SCHEDULE 13—PUBLICATION

Item 1 Subsection 9A(6)

Item 2 After section 30A

Item 3 Subsection 60(2)

Item 4 Amendments of listed provisions—publication

Item 5 Amendments of listed provisions—publication

Item 6 Application—publication

Item 7 Application—review of decisions

The CHC has no concerns with the amendments in this Schedule, at this time.

SCHEDULE 14—PUBLIC NOTIFICATION AND RECOVERY

Item 1 After paragraph 30EA(2)(b)

Item 2 At the end of subsection 30EA(2)

Item 3 After paragraph 32HA(2)(b)

Item 4 At the end of subsection 32HA(2)

Item 5 Subsection 41KA(2)

Item 6 At the end of subsection 41KA(2)

Item 7 Application of amendments

The CHC has no concerns with the amendments in this Schedule, at this time.

SCHEDULE 15—FAILURE TO COMPLY WITH REQUIREMENTS TO PROVIDE INFORMATION ETC.

Item 1 After paragraph 30(2)(c)

Item 2 After subsection 32JB(1)

Item 3 After subsection 41JB(3)

Item 4 Application of amendments

The CHC has no concerns with the amendments in this Schedule, at this time.

SCHEDULE 16—INFORMATION

Item 1 At the end of subsection 9D(7)

Item 2 Paragraph 23(2)(b)

Item 3 Application of amendments

The CHC has no concerns with the amendments in this Schedule, at this time.