Complementary Healthcare Council
of Australia

THERAPEUTIC GOODS AMENDMENT (2009 MEASURES No. 2) BILL 2009

Submission to the Senate Community Affairs Committee

Complementary Healthcare Council of Australia

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The Complementary Healthcare Council (CHC) is the expert association exclusively committed to a vital and sustainable complementary healthcare products industry. The CHC is unique in that it is the only association solely dedicated to representing the complementary medicine sector and believes in a holistic healthcare model based on promoting long-term wellness in the community.

Members of the CHC include importers, exporters, manufacturers, raw material suppliers, wholesalers, distributors, retailers, practitioners, consultants, direct marketers, multi-level marketers and consumers. The CHC is a reference point for members, the government, the media and consumers to communicate about issues relating to the complementary healthcare industry.

Summary

In principle, the CHC supports the progression of amending the *Therapeutic Goods Act 1989* (the Act) for therapeutic goods; many of the proposed amendments are long overdue and welcomed by the complementary healthcare industry. The CHC notes that many of the amendments were developed or identified under the proposed joint regulatory scheme between Australia and New Zealand (which has since been put on hold). For these amendments to be progressed in an Australian-own context, further consultation is now required.

The Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009 has identified several areas within the Act that require amending. The CHC, in general, supports the principles within the Bill however has some concerns relating to several of the proposals; these concerns have been identified and outlined in this submission.

The CHC, in general, supports the:

1. separate arrangements for the scheduling of medicines and poisons;
2. new section regarding matters which must be taken into account by the Secretary when exercising powers; and
3. delegation of the powers of the Secretary to be permitted for a person who holds, occupies, or performs the duties in a position at the Therapeutic Goods Administration (TGA) prescribed in the regulations.

Amendments outlined in the Bill which are of concern to the CHC include:

1. The TGA's administration over both the Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS).
    - The TGA is dedicated to ensuring therapeutic goods in Australia are of an acceptable standard therefore should be administering the ACMS only;
    - The ACMS should have appropriate complementary medicine representation;
2. The amendment to advertising offences capturing all persons rather than being limited to only sponsors.
    - More clarification is sought in regards to certain circumstances where advertising is deemed to be inappropriate.
3. The Minister, by legislative instrument, can specify advisory statements required to be on labels.
    - More clarification is sought as to whether legislatively underpinning advisory statement requirements will restrict this process from industry's perspective.

The amendments relating to medical devices have not been addressed in this submission as the proposals do not apply to the majority of the members we represent.

Administration of the Advisory Committee on Chemicals Scheduling

The CHC supports the intent to separate the medicines and chemicals scheduling committees however questions whether the planned administrative framework is appropriate. The CHC considers it more suitable for the ACCS to be administered by another department where chemical safety evaluation, for substances not intended to be used in therapeutic goods, is conducted as part of their current function.

The TGA's role is to assess and monitor activities to ensure therapeutic goods available in Australia are of an acceptable standard; assessments and evaluation of substances that are **not** intended for the purpose of therapeutic goods should be the responsibility of another, more relevant, department. The TGA works on full cost recovery which is supported by the therapeutic goods industry; this includes the complementary medicines sector. **The CHC does not consider it appropriate that the therapeutic goods industry will be subsidising a function not related to the therapeutic goods sector, once the current National Drugs and Poisons Scheduling Committee is separated**. There is currently a proposal for an increase to fees and charges for complementary medicines to be increased to 14.3% which will heavily impact on the industry. Given the significant impact, it is inequitable for activities such as the administration of a committee to provide recommendations on substances used in paints and detergents (for example) to be recovered through the complementary and other medicines sectors.

The CHC suggests that the Department of Health and Ageing Office of Chemical Safety and Environmental Health may be an option for administering the ACCS. This department already plays a role in:

- providing advice on the potential human health risks posed by chemicals used in the community, and establishes protective health-based standards for safe chemical use;
- conducting risk assessments for agricultural and chemicals for the Australian Pesticides and Veterinary Medicines Authority (APVMA), as part of the APVMA's registration and review processes for these chemicals; and
- determining and maintaining human health standards for chemicals, including the scheduling of drugs and poisons, and first aid instructions and safety directions for chemicals.

Given that the Bill states ACCS will not make recommendations '*in relation to substances to the extent that the substances are, or are included in, therapeutic goods,'* it would appear that the TGA are no longer the appropriate administrative department. The CHC requests that consideration be given to the above identified concerns before progressing this amendment further.

Constitution of the Advisory Committee for Medicines Scheduling

The CHC notes the new provisions outlined for the ACMS – the committee will be constituted according to the regulations and each state and territory can nominate a representative. The CHC however still has concerns regarding appropriate representation. The CHC strongly urges **there be appropriate complementary medicine representation and expertise on this committee** as it is not explicitly clear how the committee will be constituted. Substances used in complementary medicines

can be subject to the *Standard for the Uniform Scheduling of Drugs and Poisons*; to ensure the complementary medicine substance has been evaluated appropriately, a representative from the industry sector should be on the committee. Complementary medicines have various paradigms, (e.g. differing uses and methods of manufacturing) and these should be taken into consideration when assessing and evaluating such substances.

Advertising offences for inappropriate advertising of therapeutic goods

The CHC recognises that inappropriate advertising of therapeutic goods is of great concern, particularly in relation to accurate information being provided to consumers. The CHC notes that the proposed amendment will mean that offence provisions can be applied to any persons found to be inappropriately advertising a therapeutic good, not just sponsors as is the case now. The CHC acknowledges this amendment will deter sponsors from recruiting other persons to inappropriately advertise a product on their behalf, knowing that they cannot be penalised.

The CHC does however seek **further clarification as to how and when this provision will apply** as the CHC believes there may be certain scenarios where this may be difficult to administer. Without being clear as to how this provision will be administered, the complementary medicine sector cannot fully support the proposal. There may scenarios where advertisements are published in good faith however are considered to be an offence under the Act – for example: a sponsor submits an approved advertisement to an advertiser. The advertisement contains a number of indications. At the time the advertisement was cleared, the indications were included in the Australian Register of Therapeutic Goods (ARTG) for the particular product. In the meantime, the sponsor has deleted the indication from the ARTG however the advertiser is unaware of this change and has published the advertisement in good faith. The advertiser has now committed an offence and is liable under the Act.

The CHC also seeks **further clarification of a defence for an offence of this Section of the Act.** The CHC suggests that if the current wording in the proposal is to remain, a defence should be included to cover any scenarios (such as the one outlined above) where an advertisement is published in good faith. The CHC notes that the defence would only apply to a person acting bona fide in good faith where they have received written verification from the sponsor that the advertisement complies at the time of publication.

The CHC is currently working on an Advertising Reform proposal; advertising has been previously identified by the Parliamentary Secretary for Health and Ageing as an area requiring overall review and industry agrees. The CHC understands that the TGA is also looking at advertising reform and suggests that any changes to the Act relating to advertising be postponed until the review has been completed. It is possible that the advertising system, post review, put forward by industry and/or the TGA may vary from the current framework; it would therefore be more practical to suspend progression of this particular amendment until a more thorough overview of the entire process has been developed.

Legislating required advisory statements for medicines

It appears that the Bill is proposing to legislatively underpin the current document titled '*Required Advisory Statements for Medicine Labels'.* The CHC seeks **further clarification as to whether this proposal intends to alter the current process for establishing these statements and whether the**

complementary medicine industry will continue to be included in such consultations. The CHC does not support a process whereby input from stakeholders is not permitted.

The CHC supports the requirement of advisory statements (where needed) for medicines, including complementary medicines, to inform consumers and raise awareness however the CHC would like reassurance that the processes in establishing these will be done in full consultation with the complementary medicines industry.

Conclusion

The CHC supports amending the Act in principal and commends the Government for acting on progressing such changes in an Australian only context given the collapse of the Australian New Zealand Therapeutic Products Authority. Considering most of the amendments have been discussed with the anticipation of a joint regulatory scheme, further consultation is now required before implementation of such provisions in the Australian environment.

Noting the support for some of the amendments outlined in this Bill, the CHC has raised concern with several provisions:

- The CHC supports the separation of the medicines and chemicals scheduling committees. However the CHC asks the Government to reconsider the TGA's role in administering the chemicals committee given its activities are around substances **not intended for therapeutic goods** – given the TGA is fully cost recovered through the therapeutic goods industry it does not seem appropriate for this agency to be performing this activity;
- The CHC recommends the ACMS consist of appropriate representation and expertise from the complementary medicine industry;
- The CHC seeks further clarification for the proposed amendment to inappropriate advertising for therapeutic goods – the CHC considers it more appropriate for this provision to be put on hold until the advertising reform process has been completed; and
- The CHC requests reassurance that the process for establishing advisory statements be consulted broadly with industry as is current practice noting that there will be a legislative instrument outlining all required statements for medicines.

The CHC hopes that the suggestions outlined in this submission will be seriously considered before any further progression of this Bill.