Tambling responds

Senator Grant Tambling has rejected the CHC's criticism of government initiatives aimed at reforming the regulation of complementary medicines

To the Editor, Natural Health Review

I write in response to an article published in the July/August 2000 edition of N[illegible]al Health Review in which the Complementary Healthcare Council (CHC) unashamedly attempts to denigrate the reform initiatives which the federal government has introduced in complementary medicines.

I would be deeply embarrassed if the article was anything near the truth — instead it simply reflects poorly on the writer who I understand is one of the CHC's paid staff.

The article is factually flawed, heavily biased, offensive to the many industry and government people who have achieved so much in such a short span of time, and clearly reflects the current paranoia of the CHC as it battles to remain a credible player in the complementary medicines industry.

I understand that the CHC apologised to the TGA for the article which was leaked by one of the CHC's staff.

Various industry players have also apologised to me personally and indicated their surprise at the publication and tenor of the article.

This is a very disappointing lack of quality control for an organisation which claims national coverage of a vital medicines sector.

I am confident in the professionalism and outputs of TGA staff — who certainly do not deserve public derision of this sort.

Let me overview the key reforms and what has actually been achieved and address claims made in the CHC article.

The Advertising Review

A key reform was the comprehensive overhaul of the advertising arrangements for therapeutic goods.

Now complementary medicines (CMs) can make a substantially wider series of therapeutic claims subject to holding the right sort of evidence to back them up.

Claims can relate to the promotion of well being, health maintenance, risk reduction and symptomatic relief of non-serious conditions in keeping with the philosophy of complementary medicine.

As far as I can ascertain, we lead the world in providing this sort of opportunity for the CM industry.

The article claims the Code is more "restrictive" and "complex" with "few concessions to the complementary industry".

Yet Marcus Blackmore, one of the influential players in the CM industry, and the CHC has publicly declared that industry generally supports the review, agreeing that it "will allow us to make certain claims that were previously denied by government".

In numerical terms, the recent results from the six-month trial of the new advertising arrangements have shown that of the 400-odd claims presented to the 'Advisory Group' for review and advice, more than 230 are new claims that would not have been allowed under the prohibitions of the old advertising Code.

Levels of Evidence Guidelines

The advertising review has delivered clear and comprehensive guidelines for sponsors relating to the evidence required to support claims made for medicines.

If you like, it tells a sponsor what kind of scientific or traditional evidence is needed if that sponsor wants to make a therapeutic claim for its product. Allowing claims based on evidence of traditional

CHC's Report Card

Pupil: Senator Tambling

- Establish OCM 4/10
- Enhance CMEC ... 3/10
- Establish CHCF ... 6/10
- Clarify Definitions ... 5/10
- Advertising Claims ... 5/10

TEACHER COMMENT

Grant started term with great enthusiasm but has not sorted out the detail which has resulted in disappointing performance.

use is consistent with the philosophy of CMs and clearly differentiates them from other medicines.

Despite this, the CHC complains the model is too restrictive and complex for complementary medicines.

In fact, all it does is ask for statements of product effectiveness to be backed up with an appropriate level of evidence, just as you would expect for any medicine or, for that matter, any other product promising to do something for the purchaser.

And in fact, the evidence framework for scientific claims is based on the framework put forward by the former Nutritional Foods Association of Australia (now the CHC) itself.

Greater accountability in the complementary sector also reflects the greater credibility afforded the complementary sector following the introduction of the new regulations, which are more flexible and allow more claims in advertising than ever before.

The CHC also neglects to mention the almost unprecedented four-year implementation timeframe in which to implement the new Levels of Evidence Guidelines if the sponsor wasn't previously compliant.

The overall aim has been to create a level playing field for all parties involved with the supply of medicines into the Australian market — one which ensures that consumers are not misled by false and deceptive therapeutic promises.

"THE ARTICLE ... CLEARLY REFLECTS THE CURRENT PARANOIA OF THE CHC AS IT BATTLES TO REMAIN A CREDIBLE PLAYER IN THE COMPLEMENTARY MEDICINES INDUSTRY"

CMEC and the availability of new substances

Since the Complementary Medicines Evaluation Committee (CMEC) was established, 53 new substances have been approved by the TGA in the just over two-and-a-half years of CMEC's operation.

This equates to 112 new individual substances when the different forms or salts of new substances are taken into account.

None of this would mean anything unless it translates directly into products in the marketplace and to promoting the livelihood of the CM industry and the availability of CMs to the Australian public.

The new substances approved through the CMEC/TGA system have resulted in more than 1,100 new CM products being entered onto the Australian Register of Therapeutic Goods and potentially available on the market during this relatively short time. This compares with one new substance in the previous seven years.

As for the claim that there are "delays in the release of CMEC decisions", preliminary CMEC decisions are published within three working days of each meeting subject to ratification at the following meeting.

Establishment and recognition of the OCM

The establishment of the Office of Complementary Medicines within the TGA gave the CM industry for the first time a 'one-stop shop' and a recognisable presence for CMs within the reg

ulatory structure for medicines.

This occurred at the industry's request and has been widely appreciated by the sector.

The CHC article fails to acknowledge this, preferring to be negative and critical of costs and industry workloads associated with setting up this initiative, when in fact most of those costs were met by TGA resources in the first instance.

The Office handles all of the traffic to and from CMEC as well as dealing with many other policy and reform implementation issues pertinent to the sector.

The OCM has also facilitated swifter gazettal of regulatory decisions.

This was acknowledged again by Marcus Blackmore in his article in *Australian Pharmacy Trade* (June 2000) where he said the OCM "...has delivered quicker gazettal time for new substances and with the authority of CMEC... has delivered 20 new substances in the last 12 months."

The CHC's first annual report published in March of this year stated that: "Perhaps the greatest and most significant change has been the culture shift and different approach of the regulators within the TGA,

Marcus Blackmore

by a constructive and co-operative relationship, which was announced last year by the Senator as a "new partnership, between the TGA and the industry."

Can this be the same organisation that is now damning these same efforts on the part of the regulators and the government?

Electronic Lodgement Facility (ELF)

The claim by the CHC that there are delays of up to 10-12 weeks for new

around is patently untrue.

Around 80-90 percent of applications pass through the listing system in less than 20 days.

Before the instigation of the ELF system, new complementary medicine applications were taking up to four months to process.

Applications that take longer to process are generally those where the sponsor has tried to gain approval for a medicine that either does not meet, or does not appear to meet, the marketing approval criteria in relation to ingredients or claims.

The CHC's comments about the development of a system that is "just as complex and prescriptive as the previous process" are hard to rationalise when the complementary industry signed off on the proposed model for the system and when, during a recent workshop demonstrating some of the capabilities of the proposed new system, the response from sponsors was extremely positive.

The OCM has bent over backwards to introduce more streamlined administrative procedures in the day-to-day handling of these applications.

I again quote from the CHC's first

CHC claims misleading: Tambling

FURTHER TO allegations made in the July-August issue of the *Natural Health Review* (see main story), the latest claims by the Complementary Healthcare Council in the September-October issue continue to disparage the efforts of the federal government to implement regulatory reform.

The CHC's criticisms of the new arrangements for natural healthcare products — in particular its comparisons with the Canadian and New Zealand models — are misleading and irrelevant given that the Australian system was developed in 1999 after extensive consultation and investigation in concert with the CHC and other stakeholders.

The reforms that were the culmination of this work were developed with the full input

Senator Grant Tambling

of the CHC; to hear the CHC now castigate the same changes it helped put in place smacks of hypocrisy.

To illustrate the effectiveness of the new arrangements, the output of the Office of Complementary Medicine (OCM) and the TGA has been efficient and encouraging.

The result is that of more than 200 sponsors participating in the new Australian system — and may I remind readers that that includes 105 CHC members — only nine companies are currently in dispute in relation to levels of evidence and/or other problems under the new Advertising Code guidelines.

A further 10 problem issues generated by delinquent companies are currently being investigated by the TGA and OCM, which are playing very proper and correct regulatory enforcement roles, and have my full political support.

A more accurate assessment of the similarities between the Canadian and Australian models of regulation would reveal two systems that are broadly similar — Canada has an OCM not unlike Australia's — but for one significant point: Canada's OCM is still in the process of developing a regulatory framework for natural healthcare products.

As such, it is premature for the CHC to be making unsubstantiated claims as to the benefits or otherwise of an overseas model.

My discussions with New Zealand Ministers and officials obviously are more encouraging and progressive with regard to trans-Tasman harmonisation issues than a few dissenting dietary supplement spokespeople — who have voiced their opposition to Australia's OCM/TGA model — would have readers believe.

As worrying as these wildly accusative claims are, of even greater concern is the allegation by the CHC that the arrangements under the new Advertising Code are likely to cost an estimated $100,000 per company to implement.

This is patently untrue.

The only existing advertising labelling claims which need to be changed are those which do not comply with the new requirements.

Where this is the case, a generous four-year transition period has been allowed for the changeover.

(It is noteworthy that the US FDA allowed only an 11-month transition period when it introduced structure/function claims for dietary supplements earlier this year.)

Sponsors have always been required to hold appropriate evidence to support claims made in relation to their products, so there is no additional impost at all for sponsors who have products carrying claims which comply with the new arrangements.

To say that the advertising charges alone would cost $100,000 is wrong, given that companies were supposed to hold the evidence for any claims they made under the old regime.

Companies wishing to take advantage of the new regime, and gather evidence to support new claims for their products, will be making a commercial decision.

No doubt businesses will weigh up any cost in making the changes against future profits, as they would for any commercial decision.

It costs $400 to list a new product and include its indications/claims on the Australian Register of Therapeutic Goods.

I would question the credibility of any health economist who suggested that it would cost companies $100,000 to implement the new Advertising Code.

Australia's new regulatory system is world-class.

It underpins the inclusion of complementary healthcare products in the broader Australian healthcare system, offering sponsors who make therapeutic claims about their products full credibility in the competitive medicines marketplace. ■

istic letter threatening to cancel their product from the Register.

"We now have the ability to talk with the staff and are encouraged to do so, to negotiate minor changes in ELF applications.

"I have heard some industry members from across the Tasman ask, 'Is this really the TGA that we are dealing with?'

"These are very welcome changes, and we must continue to build on this constructive partnership approach."

It is also important to note that the complementary medicines industry has been fully represented during the advertising review process and through the redevelopment of the electronic lodgment facility.

The Forum

Another important reform outcome has been the Complementary Healthcare Consultative Forum, which I chair; the meeting reports are readily accessible on the TGA website.

The Forum comprises a wide range of stakeholder groups and other relevant parties and has allowed a healthy and broad exchange of ideas — with robust debate on a range of issues including research and practitioner regulation.

In fact, a joint research program with industry was mooted and progressed through the Forum out of recognition of the importance of good research to the future of the CM industry.

The government was prepared to put a million dollars on the table subject to industry matching this funding dollar-for-dollar.

In the CHC's first annual report this initiative seemed to be welcome.

The report states, "Although this might not be a lot of money in research dollars, it is the first time that the government has been prepared to contribute in this way towards CM research.

"The next steps are to raise the industry contribution and to set up a system that allows industry to have some say in the direction of the research, and how the money is to be spent."

It is most unfortunate that this opportunity to develop new indications and possibly further advertising claims for CM products looks like being missed due to claims by some CHC members that this would be another unnecessary cost burden on the industry.

This is a most short-sighted approach that is not in the long-term interests of the industry; nor does it take advantage of the opportunities available by including CMs in the National Medicines Policy

ees and charges

Let me set the record straight on this issue.

Certainly, additional fees and charges for listed medicines were agreed in January 2000 and became effective on 1 July this year.

These new fee schedules are still well below what they would have been if TGA had simply doubled the fees and charges following the government's decision to move from 50 percent to 100 percent cost recovery in 1998.

In other words, the full costs of operating the system we now have in place have not been passed on to industry.

Let me now move to dispel some other unhelpful misunderstandings.

'Separateness within' and the 'food' paradigm

The CHC has persistently voiced the view that the current model of regulation, which has the CM sector regulated under the therapeutic umbrella, is an inappropriate one.

This regulatory framework is premised on 'separateness within' the TGA system.

It is widely proclaimed by CHC's executive director Val Johanson not to be working and that what is needed is a separate system outside of the therapeutic or 'pharmaceutical' mode.

This view argues that CMs are always of low risk and not in need of such a strict system of regulation.

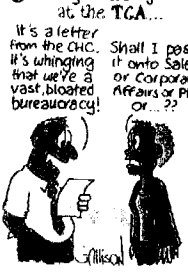
If the CHC is campaigning for less regulation or a separation of complementary medicines from TGA, then it always has the opportunity to market its members' products as foods, provided they lawfully are foods.

On the other hand, if it wants to see those products marketed as medicines with therapeutic claims, and if it wants the credibility afforded by the TGA's approval for these claims, the quality assurance through GMP accreditation and the imprimatur of expert committee (CMEC) evaluation, then it should wake up and recognise just how good the current model is in Australia and why it is leading the world in this area.

In light of the recent CHC article it is surprising that in July of this year Johanson, in a *Current Therapeutics* article, commends our Aussie system and its "strict regulatory environment that applies to complementary medicines".

She does this by acknowledging that it "...has resulted in Australian products being recognised internationally as among the highest quality in the world."

One could be forgiven for believing that the CHC message changes depending on the audience.



Public safety and CMs

CHC repeats a mantra of CMs being low-risk products needing little, if any, regulation.

A series of recent incidents, where CMs sparked public health and safety concerns on a national scale, contradict this claim.

For example, a TGA review of the safety of guarana, and the death of a young woman who drank a beverage containing guarana, led to a new label warning of the presence of caffeine.

In another case, reports of serious interactions between St John's Wort and important prescription medicines led to the requirement for a label warning and an advisory patient information sheet.

In the case of the toxic herb Aristolochia, the TGA recently tested all products on the Australian Register of Therapeutic Goods in which the herb was likely to be substituted.

It recalled eight contaminated products as a result.

Conclusion

At the outset, the government sought to achieve, through the introduction of the CM reform package, these key objectives:

- to firm up the government/industry relationship which, until this package, had been difficult and unproductive
- to more fully recognise a role for the sector under the TGA umbrella and give it credibility as a 'medicines' industry
- to raise the standards in the industry generally, from a doubtful and tentative partner to a strong contributor to healthcare arrangements.

The reforms set up new regulatory arrangements for the sector, promoting the complementary healthcare industry as a legitimate partner in the healthcare community.

The terribly disappointing thing is that, after all that work, one newer member of the medicines sector, the CHC, unlike the other peak bodies in the medicines industry, seems unable or unwilling to adapt to the new environment and work constructively with the TGA to get the best outcomes for everyone — industry, the Australian consuming public, and the government and its regulatory agencies. ■