New Head for Australian Health Watchdog

Monash University Associate Professor Ken Harvey AM is the new President of Friends of Science in Medicine (FSM).

He provided the following comments for HAIAP.

Three founding members of FSM stood down from the executive this year. They are our past President Emeritus Prof John Dwyer, past Vice-president, Emeritus Prof Alastair MacLennan and past Treasurer Prof Marcello Costa. They have kindly offered to continue their involvement as consultants.

FSM was formed in 2011. It has grown to become a major critic of unscientific health practices and fraudulent health claims. It has advised governments and media, made numerous submissions to inquiries and provided extensive public advice concerning dubious health claims and practices. It successfully advocated the removal of private health insurance taxpayer-funded rebates from 'natural' therapies that lacked evidence of efficacy.

Valuing scientific rigor is especially important in 2019 where unsubstantiated health claims are rampant and scientific consensus is 'imbalanced' by the views of extremists.

FSM campaigns against the unethical promotion of therapeutic goods and services to consumers. We critique unproven and exploitative services offered by medical practitioners, such as the infusion of intravenous vitamins and chelation therapy. We are equally concerned about Traditional Chinese Medical Practitioners claiming that acupuncture can treat infertility or Naturopaths advocating homeopathy.

We encourage tertiary institutions and students of medicine and health sciences to critically appraise therapeutic products and services as part of the courses offered. Complementary medicine provides a fertile field for students to assess the often-outrageous claims made and report regulatory breaches.

Post-marketing reviews by the Therapeutic Goods Administration (TGA) show appalling levels of regulatory non-compliance by the complementary medicines industry. The following tables are compiled from tables 25 & 26 of the TGA's Annual Performance Review.

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Compliance status determined (Listed medicines)				
	2016-17		2017-18	
No breach	87	21%	42	25%
Breach found	***330***	***79%***	***129***	***75%***
- Manufacturing, quality	62	19%	27	21%
- Labelling	94	28%	58	45%
- Advertising	86	26%	59	46%
- Unacceptable presentation	140	42%	63	49%
- Lacked evidence	180	55%	50	39%
- Safety	22	7%	0	0%
- No response	8	2%	5	4%
Total	**417**	**100%**	**171**	**100%**

Compliance status unable to be determined (Listed medicines)		
Medicines cancelled by sponsors after request for information	74	51

It is likely that many medicines cancelled by the sponsor to avoid a compliance review also had significant regulatory breaches.

The above table shows that TGA inspection of manufacturing facilities for GMP does not guarantee product quality. This was confirmed by a paper titled, "An evaluation of garlic products available in Australian pharmacies". The quality indicators evaluated in their study, including evidence for the formulation used, labelling, product, safety, manufacturing information and key constituents, varied significantly between the garlic products available in Australian pharmacies.

Understandable, consumer confidence in the complementary medicine industry, and the TGA as a regulator, leaves much to be desired. During June and July 2018, the TGA conducted its first survey of Australian adults. It employed a dual sampling methodology: a quota driven population-based sample (Panel) and an (Opt-in) sample sourced through known TGA contacts, networks and consumer stakeholders. The responses of survey participants to statements about complementary medicines follow:

Participants agree that:	Panel (n= 1,045)	Opt-in (n=684)
Complementary medicines are safe	38.5%	25.8%
Appropriately regulated	32.2%;	14.5%
Manufactured to high standard	38.4%;	14.5%
Trusted	37.6%;	23.9%
Government monitors safety	41.8%;	18.2%

Last year, the Therapeutic Goods Advertising Code Council and Complaint Resolution Panel (CRP) were abolished and from 1 July 2018 the TGA took over the advertising complaint system. Health Minister Hunt said these measures, "will enable potential harms from inappropriate advertising to be comprehensively prevented".

A preliminary analysis in mid-January 2019 showed 628 complaint outcomes with a 2018 reference number had been published on the TGA website. Four were judged not in the TGA's jurisdiction. Of the remaining

624, 10 (1.6%) were judged not to breach the Code while 614 (98.4%) did. Of the latter, 591 (96.3%) complaints were classified as low priority and closed by sending the advertiser a compliance notice with educational material. The TGA has stated that sending a compliance notice is not an official finding the Code has been breached. I find this assertion disingenuous. Why else would a compliance statement be sent?

The remaining 23 (3.7%) complaints were classified as higher priority, all were said to be closed with, or without, formal action when compliance was achieved. In my opinion, the TGA has declared compliance has been achieved on higher priority complaints, when it has not. Are the TGA deliberately minimising the number of complaints reported to breach the Code?

Regardless, this statistic of around 98% of all complaints found to breach the Code is similar to what the old Complaint Resolution Panel found. It confirms a major on-going problem with non-compliant advertising.

Conclusion

In my opinion, the TGA's new complaint system is worse than the system it replaced. Minister Hunt's hopes have not been realised. Until such time as the TGA impose penalties that outweigh the profits generated by misleading and deceptive advertising, non-compliance will continue.

Health professionals and consumers want complementary medicines that address real medical needs and deliver proven health outcomes. The current TGA trust-based, light-touch regulatory system fails to deliver this outcome. Instead, it has produced a market-place flooded with over 11,000 dubious products, marketed by celebrity endorsement and promotional hype, not clinical evidence.

The critique by Royal Commissioner Haynes on regulatory failure in Australia's financial services industry is equally applicable to the TGA. A failure to enforce the law undermines the authority of the regulator whose fundamental responsibility is to do just that. It also encourages others to break the law, leading to a race to the bottom and consumer detriment.

These are important Federal election issues. As are the comments about organisational culture by Graeme Samuel, who is about to embark on a sweeping review of the banking watchdog in response to the Royal Commission findings. A similar review of the TGA is required.