


Complementary Healthcare Taskforce Presentation

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What are complementary medicines?



Vitamins and minerals, fish oil, Western herbal medicine, Chinese traditional medicines, Ayurveda (Indian) medicines, indigenous medicines, homeopathic medicines, probiotics and aromatherapy products.

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Complementary Medicines Australia concerns:




- The revised ACCC Country of Origin Labelling (CoOL) Guidelines means over 200 licensees to the Australian Made logo are in danger of being revoked.
- This will have significant detrimental impacts on the industry's \$1.2 billion export market and threaten a work force supporting a 4.9 billion dollar industry.

<http://www.cmaustralia.org.au/Australian-Made-Issues>

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The Issue: Substantial transformation



- ACCC Guidelines:
 - ‘Substantially transformed’ means a finished product that’s **fundamentally different** from the imported ingredients that went into it.
- Federal Court ruled (03/12/2018):
 - Encapsulation in Australia of imported fish oil (from Chile) and Vitamin D (from China) was **NOT** substantial transformation.

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Complementary Medicines Australia concerns:







- Many consumers, especially those in the Asia-Pacific region, look for the 'Made in Australia' logo as proof of high quality, trusted, products synonymous with Australian complementary medicines
- The ACCC criteria for substantial transformation should be watered-down such that all finished medicinal products manufactured in Australia under GMP meet the definition.

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Four perspectives







- Consumers (Choice, TGA survey)
- Public Health (PHAA)
- South East Asian Region (Health Action International Asia Pacific)
- Friends of Science in Medicine

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Consumer Perspective (CHOICE)




- Set up by consumers for consumers, CHOICE provides Australians with information and advice, free from commercial bias.
- CHOICE fights to hold industry and government accountable and achieve real change on the issues that matter most.

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Consumer Perspective (CHOICE)



- Country of Origin Labelling (CoOL) is a priority issue for CHOICE.
- In addition, Australian Consumer Law and the Therapeutic Goods Advertising Code both state that representations must be truthful, accurate and not misleading.
- Accordingly, CHOICE supports the ACCC CoOL guideline for complementary healthcare products.

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Consumer Perspective (TGA survey)


During June and July 2018 the TGA conducted a survey of consumer opinion about CM. 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.

Overall, the responses showed considerable concerns by survey participants relating to statements about complementary medicines


Agreed with statement:	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%	20.6%
<u>Trusted</u>	37.6%	23.9%
Government monitors safety	41.8%	18.2%
Overall	37.7%	20.6%

<https://www.tga.gov.au/tga-consumer-survey-2018>

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Public Health Perspective (PHAA)




- The PHAA is the principal Australian public health NGO working to promote the health and well-being of all Australians.
- Its mission is to drive better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health.

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Public Health Perspective (PHAA)




- Position Statement
 - Food labelling is needed to assist consumers to make healthy food choices and promote public health including: ingredient labelling and nutrition information panels (including added sugar) and interpretive front-of-pack-labelling (adopted 26 September 2018).
 - Complementary medicine. Draft policy currently undergoing consideration (including CoOL).

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SE Asian Perspective (HAIAP)



- HAIAP is part of an independent global network, working to increase access to essential medicines and improve their rational use through:
 - research excellence;
 - evidence-based policy advocacy, and
 - strengthening the capacity and involvement of civil society in government decision making.

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SE Asian Perspective (HAIAP)



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SE Asian Perspective (HAIAP)

HAIAP want medicines to be:



- evidence-based,
- address real health needs,
- affordable, and
- promoted ethically, by both local and international companies.

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Does this product fit HAIAP requirements?




- Swisse Wellness, which launched in China in 2016, offers Lung Health Support with ingredients from traditional Chinese medicine.
- With the world's highest smoking rate and some of the world's most polluted cities, the Chinese market offers unrivalled opportunity for such products.

<https://assets.kpmg/content/dam/kpmg/au/pdf/2018/demystifying-chinese-investment-in-australian-healthcare-january-2018.pdf>

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CRP Complaint: Swisse Lung Health Support



- Complaint: 2018/02/006
- Claim: "Swisse Ultiboost Lung Health Support has been formulated based on scientific and traditional evidence to provide a comprehensive formula that helps protect lungs from modern environmental influences".
- I alleged that this claim breached the *Therapeutic Goods Act* 1989 s.22(5) as it refers to therapeutic uses not included on the Australian Register of Therapeutic Goods.
- It also breached the *Therapeutic Goods Advertising Code 2015*, s4(1)(b), 4(2)(a), 4(2)(c) and 4(2)(f) as no scientific evidence could be found supporting the claims made.
- TGACRP outcome (27/03/2018) "better dealt with by another authority (referred to TGA)". To-date, no outcome from TGA.

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How many Australian CMs fit HAIAP requirements?




The image displays five Australian-made complementary medicine products. From left to right: 1. 'FatBlaster FatMagnet' by naturopathica, featuring a woman's midsection. 2. 'Fusion Detox' by 康 health, described as 'ancient wisdom modern medicine', containing 60 tablets. 3. 'Nature's Way Kids Smart Vita Gummies', a multi-vitamin and veggie product for children. 4. 'Horny Goat Weed For Her' by naturopathica, intended to 'put the spark back into your love life'. 5. 'Rejoove Hangover Relief!' by naturopathica, a 'dual formula' for hangover relief.

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Friends of Science in Medicine Perspective



- We welcome and support well-conducted research into complementary medicines (CM).
- Some traditional medicines have been found to contain valuable medicinal ingredients, which have subsequently been isolated, purified and used effectively to treat disease.


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Friends of Science in Medicine Perspective

- However, FoSM deplores the current TGA "light-touch" CM policy settings:
 - No pre-market assessment of most CM.
 - Sponsors trusted to: select ingredients from the TGA's low-risk list; manufacture under GMP, and hold evidence for claims made.
 - No timely or effective penalties for regulatory breaches.
- The inevitable result:
 - Around 80% of the TGA's limited post-marketing reviews show regulatory violations (mainly no evidence to support claims made).
 - Around 98% of published advertising complaint outcomes are upheld; many more complaints have no published outcomes.
 - Research discouraged; a better return on investment comes from industry spending money on promotional hype and celebrities.
 - CM only trusted by 24% of knowledgeable consumers.

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Perverse outcomes of CM Policy




<http://www.youtube.com/watch?v=12ww26sQF7E&feature=youtu.be>

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Rules under review: What did we want?



- A regulatory system with teeth;
- That supports research;
- That provides evidence-based products that meet real health needs at an affordable price;
- Ethically promoted.

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What did we get?

During 2018-19

Review of Medicines and Medical Devices Regulation – Stage Two

Report on the regulatory frameworks for complementary medicines and advertising of therapeutic goods




Emeritus
Mr Will D
Professor
July 2018

Current Federal Health Minister
Hon Greg Hunt MP

A flurry of activity:

- The Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017.
- The Therapeutic Goods (Permissible Indications) Determination No.1 of 2018.
- The Therapeutic Goods Advertising Code Council and Complaint Resolution Panel (CRP) were abolished, the TGA took over the advertising complaint system and a TGA Advertising Consultative Committee replaced the Code Council.
- The Therapeutic Goods Advertising Code 2015 remained operational until 1 January 2019 when it was replaced by the 2018 (No 2) Code.

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Health Minister Hunt said:

Jan 2018

Review of Medicines and Medical Devices Regulation – Stage Two

Report on the regulatory frameworks for complementary medicines and advertising of therapeutic goods



Emeritus
Mr Will D
Professor
July 201


Current Federal Health Minister
Hon Greg Hunt MP

These measures:

“Will enable potential harms from inappropriate advertising to be comprehensively prevented but at the same time make it clear to industry that they have the responsibility to produce compliant advertisements in the first place.”

The accompanying paper (in confidence until publication), and surveyed consumer’s lack of trust in the TGA, suggests the Minister’s hopes have not been realised.

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Conclusion

- Consumers and health professionals in Australia and overseas want CM to be evidence-based, address real health needs, be affordable, and promoted ethically.
- CMA are essentially saying they will lose money if they stop misleading consumers about their CoOL and obey Australian Consumer Law.
- I put to the Taskforce that upholding the CoOL, thus encouraging substantial transformation, will stimulate the CM industry to produce more research-based products which, ultimately, is their only long-term future.
- I urge the Taskforce to report to government that watering-down the ACCC CoOL guidelines would not be in the interests of consumers, the industry’s future or the reputation of the Australia Made logo.

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