Regulatory Panel Discussion

Chair: Dr Ken Harvey

CAN WE DO BETTER?

Australian Skeptics

Skepticon 2019

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Background

- The peddling of unproven and often dangerous remedies has existed throughout history.
- There are always unscrupulous people prepared to take advantage of vulnerable people.
- There are always companies that put the pursuit of profit before ethical behaviour.

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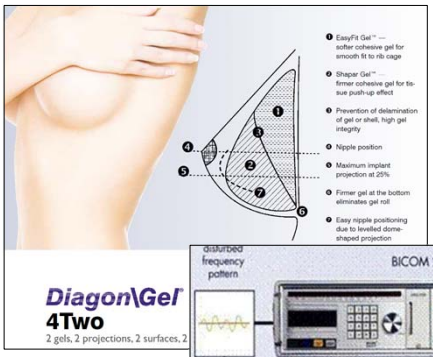
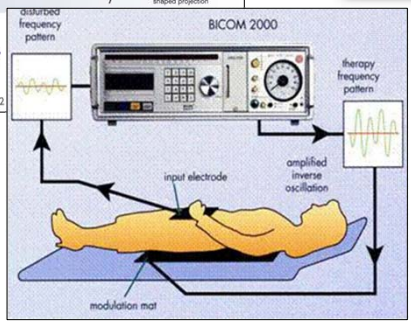
Topic: Unethical therapeutic claims about products





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The rules are good

- To be legally supplied in Australia, medicines and medical devices, must be listed, registered or included on the Australian Register of Therapeutic Goods (ARTG), overseen by the Therapeutic Goods Administration (TGA).
- It's a risk-base system.
- Registered medicines (mainly prescription medicines), labelled AUST R, are regarded as "higher-risk" and thoroughly evaluated for quality, safety and efficacy before granted marketing approval by the TGA.

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The rules are good

- Listed medicines (most complementary medicines), labelled AUST L, should only contain "low-risk" ingredients that are permitted for use by the TGA.
- They should be manufactured by a facility with a Good Manufacturing Practice (GMP) license to assure product quality.
- They can only make claims (for which the sponsor must hold evidence) for health maintenance, health enhancement, or the alleviation of non-serious, self-limiting conditions.

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The rules are good

- They should obey the Therapeutic Goods Advertising Code.
- The sponsor certifies that the goods meet all the above requirements.
- There are similar rules for medical devices.
- But, for "lower-risk" medicines and medical devices, *it's a trust-based system*.

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Is there a problem?

CRP and TGA complaint results

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Is there a problem?

TGA post-marketing surveillance

Year	Number tested+	Non-compliant #	Cancelled by sponsor
2014-15	161	73%	31
2015-16	408	80%	43
2016-17	417	79%	74
2017-18	171	75%	51
Average	289	77%	50

+ Listed products
# The commonest reasons for regulatory non-compliance were misleading labelling, packaging and advertising material, and inability to produce evidence to substantiate the claims made.

https://www.tga.gov.au/annual-performance-statistics-reports

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Is there a problem?

TGA consumer survey, June-July 2018

It employed a random population-based sample (Panel) and an Opt-in sample sourced through known TGA contacts, networks and consumer stakeholders.

Agreed with the statement: Complementary medicines are	Panel (n=1045)	Opt-in (n=684)
Appropriately regulated	32%	15%
Monitored by government for safety	42%	18%
Manufactured to a high standard	38%	21%
Trusted	38%	24%
Safe	39%	26%

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

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Who are the regulators?

ACCC AUSTRALIAN COMPETITION & CONSUMER COMMISSION SCAMWATCH

- Who oversee Australian Consumer Law.
- We have *Nicholas Heys* on the panel.

Australian Government
Department of Health
Therapeutic Goods Administration

- Who oversee Therapeutic Goods Act, regulations and Therapeutic Goods Advertising Code.
- We have *John Skerritt* on the panel.

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

- Who produce Food Standards but say they are not regulators. So we invited an academic food expert.
- We have *Julie Woods* on the panel.

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Case studies for discussion

Can we do better?

- Problems at the food-medicine interface: *Neurofolin / Sports supplements* - *Basia Diug*.
- Declaring products not to be therapeutic goods: *Excluded goods: Ear candles, Magnets, Homeopathic products?* - *Paulina Stehlik*.
- The TGA's new advertising complaint system: *Is it better than the old one?* - *Mal Vickers*.

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