Complementary Medicine: Exploring the Issues

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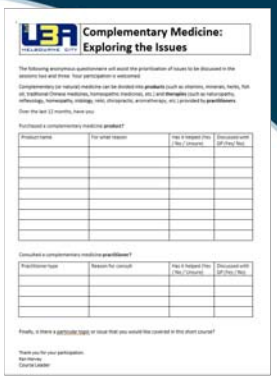
Course Leader
http://www.medreach.com.au

Short Course (1 of 3 sessions), October 2017, GAA House

MONASH University

Handouts



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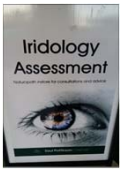
Introductions

- Let's start by introducing each of us to the group:
  - brief personal background,
  - why are you interested in complementary medicine?

3

Issues that could be explored



- What is a complementary &/or alternative medicine?
- Who uses it, why and what for?
- Regulation: products, promotion, practitioners.
- The review of the private health insurance rebate for natural therapies.
- How do we know if it works: what is evidence?
- Evidence for and against specific products &/or therapies for certain conditions.
- Sources of good information about complementary medicine, and
- Using complementary medicine wisely.

4

Dr Norman Swan asks, "What is complementary medicine?"

https://www.youtube.com/watch?v=oYeiZ8rhAFY

5

What is complementary medicine?

- Complementary medicine (CM) fits within a diverse group of health care practices and products that are not usually considered part of conventional medicine.
- Practices include acupuncture, chiropractic, homeopathy, massage therapy, meditation, naturopathy and traditional Chinese medicine.
- Products include vitamin, minerals, nutritional supplements, herbal and homeopathic medicines.
- While some scientific evidence supports some CM, for many there are key questions yet to be answered through well-designed scientific studies:
  - Are these therapies safe?
  - Do they work for the conditions for which they are used?

Classification

- NCCAM (U.S.) classifies CM therapies as follows:
  - **Alternative medical systems** such as homeopathy, naturopathy, iridology, reflexology, traditional Chinese medicine and Ayurveda.
  - **Mind-Body interventions** such as meditation, prayer, mental healing, aromatherapy, and therapies that use creative outlets such as art, music, or dance.
  - **Biologically based therapies** such as herbs, vitamins, minerals and nutritional supplements.
  - **Manipulative and body-based methods** such as chiropractic or osteopathic manipulation, and massage.
  - **Energy therapies** such as Reiki, magnet therapy, crystal healing and other invocations of electromagnetic fields.

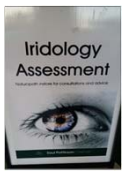
Terminology

- **Complementary** medicine is medicine used **together with** conventional medicine. An example of a complementary therapy is using aromatherapy to help lessen a patient's discomfort following surgery.
- **Alternative** medicine is used **in place of** conventional medicine. An example of an alternative therapy is using homeopathy to treat cancer instead of undergoing surgery, radiation, or chemotherapy that has been recommended by a conventional doctor.
- **Integrative medicine** combines mainstream medical therapies and CM therapies for which there is some high-quality scientific evidence of safety and effectiveness.

From: National Center for Complementary and Alternative Medicine (NCCAM), National Institutes of Health, USA: http://nccam.nih.gov/health/whatiscam/)

8

Issues that could be explored



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9

Who uses complementary medicine?

- Around 70% of 1067 nationally surveyed participants (2005) had used at least one of 17 CM therapies and 45% had visited a CM practitioner in the past 12 months.
- The annual "out of pocket" expenditure on CAM, nationally, was estimated as 4.13 billion Australian dollars (similar to co-payments on prescription drugs).
- Less than half of the users always informed their medical practitioners about their use of CM.
- The most common characteristics of CM users were: young (18-34), employed, well-educated females with private health insurance coverage and higher-than-average incomes.

Xue CCL, Zhang AL, Lin V, et al. Complementary and Alternative Medicine Use in Australia: A National Population-Based Survey. The Journal of Alternative and Complementary Medicine. August 2007, 13(6): 643-650.

10

Why do they use it?

- Push factors:
  - Difficulties in seeing GPs and specialists especially in the country,
  - Dissatisfaction with brief consultations with conventional medical practitioners.
- Pull factors:
  - Desire to take responsibility for their health,
  - Recommendations from friends, family, social networks and magazines,
  - Colocation of naturopaths with pharmacies.

McLaughlin D, Lui C, Adams J. Complementary and alternative medicine use among older Australian women - a qualitative analysis. BMC Complementary and Alternative Medicine 2012, 12:34.

11

What do they use?

- The 10 most popular forms of CM used by respondents were:
  - Nutritional supplements (46%),
  - Western massage therapy (27%),
  - Meditation (18%),
  - Western herbal medicine (16%)
  - Aromatherapy (16%),
  - Chiropractic (16%),
  - Yoga (12%),
  - Naturopathy (11%),
  - Acupuncture (9%) and
  - Chinese herbal medicine (7%).

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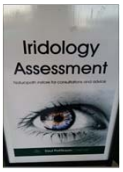
12

Why?

- Mainly for:
  - "Wellness" (younger women)
    - Dietary supplements, e.g. multivitamins,
  - Chronic musculoskeletal conditions, arthritis, aches and pain (older women)
    - Omega-3 fatty acids, glucosamine,
  - Specific needs:
    - Pregnancy (iron, folic acid, iodine),
    - Osteoporosis (Calcium, Vitamin D).
- Less likely for conditions with clear treatment guidelines for conventional medicine:
  - Diabetes,
  - Hypertension,
  - Asthma.

13

Issues that could be explored



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14

Regulation

- ***Products***

Of the numerous formulations of glucosamine available in the Australian market; which should I choose?
And does an Aust L or Aust R number make a difference?

15

Regulation of CM products

https://www.youtube.com/watch?v=oYeiZ8rhAFY

16

Recap: Therapeutic goods regulation

- In Australia, the Therapeutic Goods Administration (TGA) is responsible for regulating therapeutic goods including medicines (prescription, OTC and complementary), medical devices, blood and blood products.
  - "Complementary medicines" (CMs) contain herbs, vitamins, minerals, nutritional supplements and traditional medicines such as homoeopathic products.
- Unless specifically exempt or excluded, all therapeutic goods must be registered, listed or included on the Australian Register of Therapeutic Goods (ARTG) prior to their supply.
- The TGA does not regulate healthcare practitioners.

Therapeutic goods regulation

- The TGA uses a risk-based pre-market assessment of therapeutic goods.
- Registered medicines (labelled AUST R) are thoroughly evaluated for quality, safety and efficacy prior to market release (with the exception of some "grandfathered" products)
- All prescription medicines are AUST R.
- Listed medicines (labelled AUST L) are regarded as lower risk self-medication products. They are required to meet quality and safety standards but are not accessed for efficacy.
- Most CMs are listed (AUST L) on the ARTG.

18

Therapeutic goods regulation

- The TGA's electronic listing facility (ELF) allows listed medicines rapid and low cost entry onto the ARTG.
- They have no independent pre-market assessment.
- Sponsors self-certify via ELF that:
  - Their product is manufactured according to GMP standards;
  - The ingredients are picked from a consolidated list that the TGA regards as relatively low risk;
  - Their products only carry indications and claims for the symptomatic relief of conditions (but not for proscribed serious disease, disorders, or conditions), health maintenance, health enhancement and risk reduction;
  - They hold evidence sufficient to substantiate that the indications and claims are true, valid and not misleading.

19

Therapeutic goods regulation

- **Medical devices** are regulated by the TGA using a risk classification system:
  - Class I (low-risk),
  - Class IIa (low-medium risk),
  - Class IIb (medium-high-risk),
  - Class III (high-risk),
  - AIMD (Active implantable medical device).
- Certification (evaluation) by the TGA or an overseas notified body is required for higher risk devices.
- As with Listed complementary medicines, sponsors of lower-risk devices self-certify they are "fit for purpose".

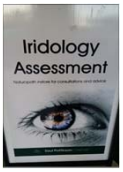
20

Problems with the system

- Self-certification by the sponsor of so-called "low-risk" therapeutic goods depends on trust.
- TGA compliance activity more than doubled from 212 (2014–2015) to 473 (2015–2016).
- Medicines with verified compliance breaches increased from 73% (2014–2015) to 80% (2015–2016).
- Labelling, advertising and evidence continued to be the major compliance breaches.
- In addition, for 2015–2016, the Therapeutic Goods Advertising Complaint Resolution Panel found 98% of 141 complaints justified (and a 40% non-compliance rate with Panel 'requests' for redress).

21

Issues that could be explored



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22

Regulation of promotion

- Therapeutic Goods Advertising Code
  - Aim: the marketing and advertising of therapeutic goods to consumers should promote rational use, be socially responsible and not mislead or deceive the consumer.
- Underpinned by legislation
  - Therapeutic Goods Act 1989 (TGA) and the Competition and Consumer Act 2010 (ACCC).
- Limited pre-clearance by industry associations of advertisements for medicines (but not devices) in some media such as print and TV (but not the Internet).

Therapeutic Products Advertising Complaints
COMPLAINTS RESOLUTION PANEL

23

Problems with promotion

Outcome of complaints

- The CRP is under-resourced, over-loaded and lacks power to enforce sanctions.
- It can take 6-12 months for complaints to be heard and the determination made public.
- Non-compliance with CRP "requests" is common; these are passed to the final regulator, the TGA.
- The TGA conducts its own investigation which can take another 6-12 months.
- If the TGA agrees with the TGACRP they can issue a "Regulation 9 order" which is meant to compel compliance. But companies can (and do) appeal to the Minister &/or the Administrative Appeals Tribunal which further delays and resolution.
- Meanwhile, misleading promotion continues.

24

Sambucol
Outcome of complaints

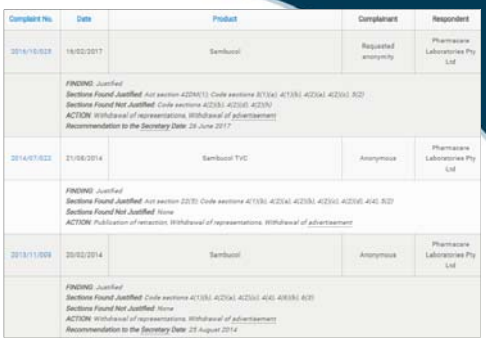
https://www.youtube.com/watch?v=jaQyrLzjvRs

25

Problems with the complaint system

3½ years later

http://pharmacycentral.com.au/sambucol-cold-and-flu-liquid-extract-120ml.html#.WYexBoiGO70
Etc.



26

Problems with promotion

Homeopathy websites ignore retraction orders

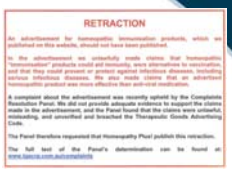
Australian Broadcasting Corporation Print Email
Broadcast: 08/04/2010
Reporter: Steve Cannane

The Therapeutic Goods Administration is being criticised after revelations that last year a third of the companies found to have breached advertising rules failed to publish retractions and withdraw misleading information.

Transcript

TONY JONES, PRESENTER: The panel that handles complaints against misleading advertisements for medical products and services is being criticized tonight for failing consumers.

Lateline can reveal that last year a third of the companies were found to have breached the Therapeutic Goods Administration's rules on advertising and they failed to publish retractions and withdraw misleading information.



FRAN SHEFFIELD: Well, obviously I'm disagreeing with them, and that's why the retraction hasn't gone up.

http://www.abc.net.au/lateline/content/2010/s2867990.htm

27

Shonky medicines listed on the ARTG

28

Shonky devices included on the ARTG

- Detox foot patches
- Ear candles
- Magnets
- Electro-dermal devices
- Bio-energy devices
- Electro-acupuncture
- Frequency micro-current devices
- Haemaview diagnostic devices
- Etc, etc

29

Problems with the system

- In short, the current "light-touch" regulation of CM, especially the lack of timely and significant penalties for breaches of the Therapeutic Goods Advertising Code and the Therapeutic Goods Act, encourages unscrupulous sponsors to flood the market with shonky products and unethical claims.
- Research has shown that the public does not understand the difference between AUST R and AUST L labelled products.
- Thus, there is currently little incentive for CM sponsors to undertake expensive research, compile an extensive dossier and pay the higher fees required for TGA registration.
- A better return on investment comes from spending the money on celebrities, promotion and appeals.

Media perceptions

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

31

Rules under review?

Date	Initiative
2002	Report of a Review of Advertising Therapeutic Products in Australia and New Zealand
2003	Report of Expert Committee on Complementary Medicines in the Health System
2005	Description of the joint (Trans-Tasman) regulatory scheme for the advertising of therapeutic products
2006	Consultation (Draft) Regulation Impact Statement on the proposed amendments to the current regulatory system for herbal and homoeopathic medicines in Australia
2007	Consultation - draft (Trans-Tasman) advertising rule
2008	Regulation of homoeopathic and anthroposophic medicines in Australia
2009	Draft Guideline for Levels and Evidence for Listed Medicines with Indications & Claims for Weight Loss
2010	TGA Consultation: Improving advertising arrangements for therapeutic goods
2011	Consultation and Report of the Working Group on Promotion of Therapeutic Products Report of the Review to improve the transparency of the Therapeutic Goods Administration ANAO Report. Therapeutic Goods Regulation: Complementary Medicines TGA reforms: A blueprint for TGA's future
2012	Delivering reforms - Implementation plan for TGA Reforms TGA Advertising regulatory framework: Options for reform
2013	TGA Consultation Regulation Impact Statement: Regulating the advertising of therapeutic goods to the general public
2014	Expert Review of Medicines and Medical Devices Regulation (Government de-regulation agenda) Australian and New Zealand Governments agreed to cease efforts to establish a joint therapeutic products regulator
2015	Expert Review of Medicines and Medical Devices Regulation: recommendations and public forum.

What did we want?

- A regulatory system with teeth!
- Mandatory labelling, "This product has ***NOT*** been evaluated by Australian Health Authorities to see if it works".
- Legislation for timely and meaningful sanctions for advertising violations (civil penalties, enforceable undertakings).
- Increased and better targeted post-marketing surveillance and transparent reporting of problems and cancellations.

33

What did we get?

Current TGA consultations

- The regulatory framework for advertising therapeutic goods
  - Abandoning pre-approval of the advertising of therapeutic products
  - Disbanding the current mechanism for managing complaints. See also: Consultation: Amendments to the Therapeutic Goods Advertising Code (upcoming)
  - Stronger compliance powers against misleading advertising. See also: Consultation: Enhancing sanctions and penalties in the Therapeutic Goods Act 1989.
- Reforms to the regulatory framework for complementary medicines: Assessment pathways
  - The establishment of a limited list of permitted indications; restricting companies to pre-approved, "low-level" indications (see also: Consultation: Draft list of permitted indications)
  - A new pathway by which sponsors can apply for "intermediate-level" health claims that fall outside the permitted list (above) together with the publication of a "claimer" and a period of market exclusivity.
- Options for the future regulation of 'low risk' products
  - Which may be subject to a level of regulation which is not commensurate with the risk posed by these products to Australian consumers.

35

The battle continues

THE CONVERSATION

choice The People's Watchdog

Consumers Health Forum of Australia

Australian Skeptics

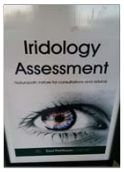
Friends of Science in Medicine

ABC TV THE 99c CHECKOUT

- While the government accepted most (but not all) the MMD recommendations their implementation is currently being contested by stakeholders in their responses to ongoing TGA consultations.
- Legislative changes will be required for implementation giving the government (and industry) additional opportunities to deregulate and cut "red tape".
- There is an ongoing need to keep the pressure up on both the government and the TGA by continuing to submit complaints, monitoring the outcome and engaging consumers and the media on these issues.

36

Next session



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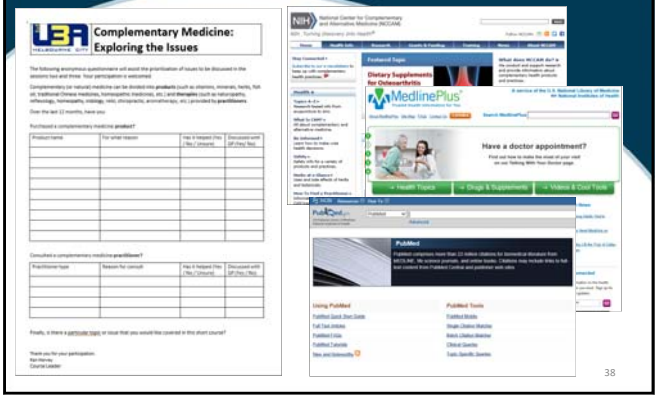
37

Third session: Evidence for specific products &/or therapies



38