Complementary Medicine: Exploring the Issues

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Disclosure of interests

• Member:
  – WHO Ethical Criteria for medicinal drug promotion.
  – Therapeutic Guidelines Limited.
  – PHARM Committee that devised the Quality Use of Medicines plank of Australian Medicines Policy.

• Consumer rep (Choice, CHF):
  – Government Working Group on Promotion of Therapeutic Products.
  – TGA Transparency Review Panel.
  – Government Natural Therapy Review Advisory Committee.
Issues that could be explored

- What is complementary &/or alternative medicine?
- Who uses it, why and what for?
- Regulation of products and practitioners;
- The current 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.

Dr Norman Swan asks, “What is complementary medicine?”

https://www.youtube.com/watch?v=0YeI8rhAFY
What is complementary medicine?

• Complementary medicine (CM) fits within a diverse group of health care systems, practices, and products that are not usually considered part of conventional medicine.

• These include vitamin, mineral and other supplements, massage therapy, meditation, Western herbal medicine, aromatherapy, chiropractic, naturopathy, homeopathy, acupuncture and traditional Chinese medicine.

• 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, food and vitamins.
  – 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.


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.

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.

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%).
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.

Issues that could be explored

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  • Regulation of products and practitioners;
• The current review of the private health insurance rebate for natural therapies;
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• Using complementary medicine wisely.
Regulation of products and practitioners

- **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?

https://www.youtube.com/watch?v=oYeiz8rhAFY
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.

- 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.
• 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.

• 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”.
Problems with the system

• Self-certification by the sponsor of so-called “low-risk” therapeutic goods depends on trust.
• The TGA can only perform limited post-marketing reviews of around 1600 newly listed complementary medicines each year.
• Until recently these results have been regarded as “commercial-in-confidence”.
• A 2011 the ANAO noted that the TGA had found high levels of regulatory non-compliance (up to 90%) in small samples.
• More recently (September 2012 to December 2013), 249 post-marketing reviews of listed complementary medicines were undertaken by the TGA; 69% had regulatory violations.
• Of 121 regulatory violations analysed in 2013, 76% related to labelling and advertising violations, including inadequate evidence to substantiate the claims made.

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).
Problems with promotion

- The TGACRP is under-resourced, overloaded 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.
- Since November 2010 there have been at least 88 complaints sent to the TGA because of non-compliance with CRP determinations but currently only 24 “outcomes” have been reported on the TGA web site. [http://www.tga.gov.au/industry/cm-cancellations-cr.htm](http://www.tga.gov.au/industry/cm-cancellations-cr.htm)
- Some of these complaints have taken several years to resolve while others are ongoing because of appeals.

Homeopathy websites ignore retraction orders

Australian Broadcasting Corporation
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 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](http://www.abc.net.au/lateline/content/2010/s2867990.htm)
Problems with the TGA

• The TGA’s “risk-based assessment” is judged solely on the likelihood of the therapeutic good to produce physical adverse effects.
• Other “risks” are not taken into account:
  – Providing an imprimatur for shonky products, “approved by the TGA”;
  – Consumers forgoing evidence-based treatment to the detriment of their health (and sometimes life) while pursuing quackery;
  – Wasting consumers money.

Shonky medicines listed on the ARTG
Shonky devices included on the ARTG

Detox...For OPTIMUM HEALTH

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

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

- SensaSlim banned after medico's exposure of bogus scientific claims
- Swisse Vitamins highlights the failure of industry self-regulation
- TGA, once again, fails to reign in shonky weight-loss product
- Adverts pulled from TV after public backlash
- Supplement regulation by TGA is completely cactus...
- Berocca fights Therapeutic Goods Administration ruling that ads breached the advertising code
- Academic quits over Swiss deal with uni

http://www.youtube.com/watch?v=12ww26sQF7E&feature=youtu.be
## A decade of procrastination

<table>
<thead>
<tr>
<th>Date</th>
<th>Initiative</th>
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<tbody>
<tr>
<td>2002</td>
<td>Report of a Review of Advertising Therapeutic Products in Australia and New Zealand</td>
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<td>2003</td>
<td>Report of Expert Committee on Complementary Medicines in the Health System</td>
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<td>2005</td>
<td>Description of the joint (Trans-Tasman) regulatory scheme for the advertising of therapeutic products</td>
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<td>2006</td>
<td>Consultation (Draft) Regulation Impact Statement on the proposed amendments to the current regulatory system for herbal and homoeopathic medicines in Australia</td>
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<td>2007</td>
<td>Consultation - draft (Trans-Tasman) advertising rule</td>
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<td>2008</td>
<td>Regulation of homoeopathic and anthroposophic medicines in Australia</td>
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<td>2009</td>
<td>Draft Guideline for Levels and Kinds of Evidence for Listed Medicines with indications and Claims for Weight Loss</td>
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<td>2010</td>
<td>TGA Consultation: Improving advertising arrangements for therapeutic goods</td>
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<td>2011</td>
<td>Consultation and Report of the Working Group on Promotion of Therapeutic Products</td>
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<td>Report of the Review to improve the transparency of the Therapeutic Goods Administration</td>
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<td>ANAO Report. Therapeutic Goods Regulation: Complementary Medicines</td>
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<td>TGA reforms: A blueprint for TGA’s future</td>
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<td>2012</td>
<td>Delivering reforms - Implementation plan for TGA Reforms</td>
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<td>TGA Advertising regulatory framework: Options for reform</td>
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<td>2013</td>
<td>TGA Consultation Regulation Impact Statement: Regulating the advertising of therapeutic goods to the general public</td>
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## What do consumer groups 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.
What did we get?


What did we get?

Complementary medicines: Cancellations from the ARTG following compliance review

Section 244 of the Therapeutic Goods Act 1989 (Cth) (the Act) provides for a person whose interests are affected by a decision made under the Act to make a request for an internal review of the decision within 60 days of the decision being notified. Such a person may seek a review by the Administrative Appeals Tribunal (AAT) of the decision by the Minister/Secretary on the internal review.

May 2014

<table>
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<tr>
<th>Date of cancellation</th>
<th>ARTG I. N. No.</th>
<th>Product name</th>
<th>Sponsor name</th>
<th>Type of classification</th>
<th>Grounds for cancellation</th>
<th>Comments</th>
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<tr>
<td>16/05/2014</td>
<td>370553</td>
<td>PharmaX Flow A</td>
<td>PharmaX Flow A</td>
<td>Terminally Terminally</td>
<td>As there were insufficient grounds to support the classification for the new product, the cancellation was reversed.</td>
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April 2014
What did we get?

The 2012 Choice Shonky award for Woo water goes to... Nature’s Way Kids Smart Natural Medicines


What did we get?

Decisions in relation to complaints about advertisements (sorted by date)

Decisions under Regulation 9 of the Therapeutic Goods Regulation 1990 in relation to complaints about advertisements

2014

- Hippocrates Natural Vitamin D3 - Hippocrates Health Centre of Australia Pty Ltd - Complaint No. 2013-05-022 (21 May 2014)
- Nature’s Way Kids Smart Natural Medicine Range - Pharmacy Care Laboratories Pty Ltd - Complaint No. 2011-10-027 (9 May 2014)
- Mugalydrate - Vitality Plus Australia Pty Ltd - Complaint No. 2012-05-012 and 2012-06-026 (9 May 2014)
- Reducta - Pharmacy Care Laboratories Pty Ltd - Complaint No. 2012-05-012 (9 May 2014)
- Once Off head lice lotion and Decontaminating Gel - P & G Australia Pty Ltd - Complaint No. 2012-05-022 (9 May 2014)
- Institute of Joan Kegworth and Company No. 2011-07-023 (9 May 2014)
- Hope’s Relief Cream - Body science - Complaint No. 2013-10-01 (9 May 2014)
- Nurofen - Reckitt Benckiser (Australia) Pty Ltd - Complaint No. 2013-12-01 (9 May 2014)

- Complaint to CRP 2011-10-027
- CRP determination 2012-03
- CRP to TGA re non-compliance 2012-08
- Regulation 9 order 2013-06
- Regulation 48 review 2013-09
- Order upheld and final compliance 2013-12
The battle continues:

- We await with interest the government’s response to the TGA's advice concerning advertising RIS options and other consultations.
- Meanwhile, complaints, assessment of regulatory performance and use of the media are being ramped up in 2014.

Swisse Chlorophyll

http://www.abc.net.au/tv/thecheckout/clips/
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Specific products &/or therapies: Evidence?