Drug promotion, advertising and ethical relationships with industry

Dr Ken Harvey MB BS, FRCPA
Adjunct Associate Professor, School of Public Health and Preventive Medicine
http://www.medreach.com.au

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.
The problem

- The peddling of unproven and often dangerous medicines, has existed throughout human history.
- There are always unscrupulous people who wish to take advantage of the desperation and grief experienced by patients with chronic or incurable disease (and their families).
- There will always be companies that put the pursuit of profit before ethical behaviour.
- There are also pressures on researchers and the media to present preliminary research in the most promising light without the caveats that should apply.

The solution: medicines policy

1. Medicines of high quality, safety and efficacy
2. Equitable & timely access to necessary medicines
3. Rational drug use (quality use of medicines)
4. A viable and responsible local pharmaceutical industry
Resolution 60.16:
- Wishing to promote evidence-based rational use of medicines by providers and consumers;

**URGES** Member States to:
- Enact new, or enforce existing, legislation to ban inaccurate, misleading or unethical promotion of medicines,
- Monitor drug promotion;
- Develop and implement programmes that will provide independent, non-promotional information about medicines.

What about Australia?

“There is an integrated three-tier system of controls for the advertising of therapeutic goods in Australia”.¹

- **Self-regulation (promotion to health professionals)**
  - Industry Codes and complaints panels in nine sectors: Medicines Australia, GMIA, ASMI, CHC, MTAA, AusBioTech, IVD Australia, ADA, ACCORD.

- **Co-regulation (promotion to consumers)**
  - Therapeutic Goods Advertising Code (TGAC), Complaints Resolution Panel (CRP) and TGA.

- **Regulation (legislation)**
  - *Therapeutic Goods Act 1989 (TGA)* and *Trade Practices Act, 1974* now renamed the *Competition and Consumer Act 2010 (ACCC).*

Self-regulation: Pros

“The Australian Government’s preference is to maintain an emphasis on self-regulation”.


- The government does not pay the cost (however, the cost to industry is passed on to consumers regardless);
- May be more flexible and less intrusive than government legislation / regulation;
- Ownership of a code may produce a stronger commitment for members to comply;
- Complaint handling procedures under a self-regulatory code can be more cost effective, time efficient and user friendly in resolving complaints than government bodies.

Self-regulation: Cons

There are nine therapeutic goods industry self-regulatory codes
Self-regulation: Cons

• Code content, monitoring, complaint procedures and transparency vary across industry sectors (“not a level playing field”).
• Codes often lag behind consumer and health practitioner views due to the absence of external stakeholders.
• Codes also lag behind the views of more progressive companies because of the need for revisions to be approved by a majority of member companies.
• Codes don't apply to non-members; a major problem in some sectors of the therapeutic goods industry.
• Numerous sector based industry Codes make it difficult for HCPs and consumers to know where to send complaints.

Self-regulation: Cons

• Medicines Australia maximum fine for a severe breach of their Code is $300,000 (with an average fine around $50,000).
• This stands in stark contrast to the recent GSK fine of $3 billion by the U.S. Justice Department – which also included GSK entering into a five-year Corporate Integrity Agreement which stipulated major changes to the way the company does business and further penalties for non-compliance).
• Over the last few years settlements for criminal and civil monetary penalties from the U.S. pharmaceutical industry reached a total of $13 billion.
Over the last few years pharmaceutical companies have paid over $13 billion to resolve U.S. Department of Justice allegations of fraudulent and unethical marketing practices.

- Trials manipulated; negative results suppressed.
- Journal articles “ghost-written”.
- Off-label promotion.
- Well paid, but undeclared, medical opinion leaders used to promote company products (educational mercenaries).
- Excessive hospitality, kickbacks, bribery.
- Consumer groups manipulated.
- Spurious patents and legal challenges to delay the entry of generics.

Sources:

- BMJ 2003;326 (31 May)
- http://projects.propublica.org/graphics/bigpharma
Problems with drug promotion to doctors

- Some 80-95% of doctors regularly see industry reps despite evidence that their information is overly positive and prescribing habits are less appropriate as a result.
- Many doctors receive multiple gifts from therapeutic goods companies every year, yet most doctors deny their influence despite considerable evidence to the contrary.

An industry that spends twice as much money on marketing than on R&D:
- distorts the information flow to health professionals (and consumers),
- creates unhealthy and expensive prescribing and consumption habits, and
- consumers expectations of a "pill for every ill".
Hence the “No Advertising Please” Campaign

- Justin conceived this campaign in February 2014 and gathered together a number of like-minded supporters, of which I was one.
- Justin is a GP and educator at Inala Indigenous Health Service, a senior lecturer at Griffith University and University of Queensland and also a medical writer. See: http://drjustincoleman.com/about/
- Before a career change into medicine, Dave had an extensive career in advertising and media. He’s now in his fifth year of medicine at the University of New England.
Campaign launch
October 2014

http://www.abc.net.au/7.30/content/2014/s4103981.htm

Campaign “misguided and dangerous”

- “The campaign to stop doctors learning about new treatments from medicines companies is misguided and potentially dangerous for patients”.
- “Barring contact with company representatives would be like having open heart surgery knowing the surgeon hasn’t been taught how to use the equipment by the people that made it”.

Dr Martin Cross
Chairman, Medicines Australia

Drug reps: Education or promotion?

- Consenting GPs and drug reps were asked to tape record their interaction.
- Sixteen audio-recordings of drug reps detailing 64 medicines, were obtained; 38 of the 64 products were prescription-only medicines.
- Information on indications and on dosage and administration was commonly provided, but information on other areas of drug knowledge, particularly product risk, was minimal.
- Thirteen presentations contained at least one inaccuracy when compared with Australian Approved Product Information.
- GPs rarely asked critical questions of the drug rep.

Roughead EE, Gilbert AL, Harvey KJ. Int J Health Serv. 1998;28(2):269-79

World Health Assembly 2007

Resolution 60.16:
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- URGES Member States to:
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Independent information

Which is why we advocate:

FREE YOURSELF FROM DRUG REPS
Dr Brian Morton
AMACGP Chair said:

• “I think the campaign is a bit silly. It’s insulting to doctors”.

• “There’s very little that they (drug companies) can offer as an inducement anymore and that’s quite a good thing. It keeps everyone honest. The types of things are a simple meal, lunch, an educational meeting after surgery”.

• Pharmaceutical companies spent $33.4 million on educational events for healthcare professionals (HCPs) between Oct 2014 and Mar 2015.

• The average cost per head was $90.

• However, some companies sponsor only a few events, but spend large sums, especially for key opinion leaders:
  – Pfizer spent $173,000 sending 13 rheumatologists to a conference in Boston ($13,308 per head)
  – Roche spent $120,000 sending 13 pharmacists to a conference in San Francisco ($9,231 per head)
  – Gilead spent $282,000 on a sexual health meeting for 82 HCPs in Melbourne ($3,430 per head)

“There’s very little inducement anymore”

- From 1 Jan 2014 to 31 Dec 2014:
  - HCP consulting fees: $1,916,434
  - Hospitality for HCP consultants: $653,749
  - Total cost of consultancy services: $2,577,525
  - Number of HCP consultants: 973
  - Average cost of HCP consultants per head: $2,649.
- However, some companies paid more for their consultants:
  - AstraZeneca spent $625,000 on 60 consultancies (on average $10,417 each)
  - Pfizer spent more than $320,700 for 50 consultancies (on average $6414 each)
  - Servier had the most number of HCP consultancy services at 142 and spent $184,129 on them (on average $1297).


“There’s very little inducement anymore”

- How do HCP consultants earn their money?
- The following list is not exhaustive.
  - Developing and/or presenting a company submission to the Pharmaceutical Benefits Advisory Committee.
  - Developing a continuing education program.
  - Writing or reviewing a scientific paper, promotional or educational material.
  - Expert opinion provided by one or more healthcare professionals on an ad hoc basis.
  - Independent grant review committee.
  - Market research where the company has selected the healthcare professionals participating in the research.

“There’s very little inducement anymore”

- An advisory board is a meeting of HCP with specific expertise contracted to meet at regular intervals to provide advice on a company’s product or group of products.

- For 6 months from Oct 2014 to March 2015:
  - Advisory board sitting fees: $1,617,681
  - Advisory board hospitality: $481,173
  - Total cost of meetings: $2,413,252
  - Number of attendees: 973
  - Average cost of hospitality per head: $495
  - Average cost of advisory board per head: $2,480.

Hence the need for disclosure

- The U.S. Physician Payment Sunshine Act is now operational.

- It requires pharmaceutical and device companies to report to the Centers for Medicare and Medicaid Services (CMS) all payments, or other transfers of value, made to individual doctors and teaching hospitals that total more than US$100 per year.

- Companies had to start collecting the information for 2012 by August 1, 2013 and report it to the CMS by March 31, 2014.

- On September 30, 2014, CMS reported 2012 payment information for the first time; 2013 are also available.
U.S. Open Payment system: an example

- Twenty-nine different drug companies paid nephrologist Ana Stankovic $594,363 in 2014, mostly for promotional speaking and consulting, but also for travel expenses and meals. She ranked about 250th among 606,000 doctors who received payments nationwide last year.
- What was more remarkable, though, was that she received payments on 242 different days, nearly every workday of last year.
- Reached by telephone she declined to comment.

http://www.propublica.org/article/a-pharma-payment-a-day-keeps-docs-finances-ok

In Australia:

- The 17th Code Edition incorporated aggregate disclosure of payments, but not individual.
- The 18th Code Edition (2015) finally required member companies to collect and report specified payments to HCPs (who agree) from October 2015.
- Following a 12 month adjustment period, from October 2016, the Code will require mandatory reporting of all specified payments to HCPs.

http://registers.accc.gov.au/content/index.phtml/itemId/1179619/fromItemid/278039
It takes two to tango

http://www.healthyskepticism.org/pharmaphacts/
Drug promotion to consumers

“There is an integrated three-tier system of controls for the advertising of therapeutic goods in Australia”.¹

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– Regulation (legislation)


Drug promotion to consumers

• Direct to consumer advertising of prescription drugs is not allowed.

• Therapeutic Goods Advertising Code applies
  – 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 in print and TV (but not the Internet).
Problems with promotion

• The TGACRP 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.
• Since November 2010 there have been many complaints sent to the TGA because of non-compliance with CRP determinations but currently less than half of the “outcomes” have been reported on the TGA web site: [http://www.tga.gov.au/decisions-relation-complaints-about-advertisements-sorted-date.](http://www.tga.gov.au/decisions-relation-complaints-about-advertisements-sorted-date).
• Some of these complaints have taken several years to resolve while others are ongoing because of appeals.

35

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)

36
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

TGA, once again, fails to reign in shonky weight-loss product

Swisse Vitamins highlights the failure of industry self-regulation

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 Swisse deal with uni
### Rules under review?

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<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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<tr>
<td>2003</td>
<td>Report of Expert Committee on Complementary Medicines in the Health System</td>
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<tr>
<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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<tr>
<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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<tr>
<td>2010</td>
<td>TGA Consultation: Improving advertising arrangements for therapeutic goods</td>
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<tr>
<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></td>
<td>TGA Advertising regulatory framework: Options for reform</td>
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<tr>
<td>2013</td>
<td>TGA Consultation Regulation Impact Statement: Regulating the advertising of therapeutic goods to the general public</td>
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### A decade of procrastination

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

What did we get?
The battle continues

• While the TGA is slowly adopting greater regulatory rigor towards complementary medicines, industry has been slow to adopt TGA evidence guidelines and we still lack timely and effective sanctions for regulatory breaches.

• Legislative changes are required yet the government (and industry) wants to deregulate and cut “red tape”.

• There is an ongoing need for civil society organisations to keep the pressure up on both government and the TGA by engaging consumers and the media in these issues, submitting complaints and monitoring the outcome.

In conclusion: Get involved

http://noadvertisingplease.org/get-involved/
Bad Pharma
Ben Goldacre
Bestselling author of Bad Science

How drug companies mislead doctors and harm patients

https://en.wikipedia.org/wiki/Bad_Pharma

Understanding and Responding to Pharmaceutical Promotion
A Practical Guide

http://noadvertisingplease.org/

http://www.haiweb.org/03_other.htm