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Australian Skeptics

Standing up for the evidence: Health Activism

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<http://www.medreach.com.au>

ANZCA, Faculty of Pain Medicine, Refresher Day , May 3, 2013

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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 representative (Choice):
 - Government Working Group on Promotion of Therapeutic Products.
 - TGA Transparency Review Panel.
 - TGA Working Group on Regulatory Framework for Complementary Medicines.
 - Government Natural Therapy Review Advisory Committee.

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Two issues: 1. Transparency

Mea culpa: are multi-billion dollar fines forcing drug companies to clean up their act?
 BMJ 2012; 345 (Published 18 July 2012)

PARLIAMENT OF AUSTRALIA

Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013

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Two issues: 2. TGA reform

25 November 2011, 2:54pm AEST
SensaSlim banned after medico's exposure of bogus scientific claims

22 October 2012, 11:05am AEST
TGA, once again, fails to reign in shonky weight-loss product

12 April 2013, 10:59am EST
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April 30, 2013
Adverts pulled from TV after public backlash

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U.S. Fines

Big Pharma's Big Fines

Company	Year	Fine (Millions of Dollars)
Eli Lilly	2009	\$142
Pfizer	2009	\$2.3
AstraZeneca	2010	\$12
Merck	2011	\$96
Abbott	2012	\$1.6
GlaxoSmithKline	2012	\$3

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Conduct leading to the U.S. fines

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

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Medicines Australia Code Edition 17, 2012




- New code incorporates aggregate disclosure of payments to health care professionals (HCP).
- However, many consumer and health professional groups argued for full disclosure of payments to individual HCP, both in the 16th Edition (2009) Code revision and again in the 17th Edition (2012) Code revision.
- MA have set up a Transparency Working Party to put forward possible models of increased disclosure by December 2013.

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Compare with U.S.

- In 2009, Merck discloses \$3.7m paid to U.S. doctors for speeches over three months.
 - The list includes the names of the individuals, the number of events at which they spoke, the payments they received, and the general topics on which they spoke (such as “diabetes,” “HPV,” or “respiratory”).
- This followed Eli Lilly in disclosing payments to doctors who speak for companies.
- Pfizer and GlaxoSmithKline have promised to make similar disclosures.
- The U.S. Physician Payment Sunshine Act (2010)
 - Requires yearly reporting of all physician payments over a cumulative value of \$100 dollars with data reporting starting in 2013.

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Transparency Working Group



- Report to Medicines Australia Board and members: June 2013.
- Consultation with members and public and adoption (hopefully) in new Code revision late 2014.
- Start recording details of payments from Jan 1, 2015.
- Public reporting on Medicines Australia web site to start in 2016 (compared to 2014 in the U.S.)

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Problems with self-regulation

- Code content, monitoring, complaint procedures and transparency vary across industry sectors (“not a level playing field”).
- Numerous sector based industry Codes make it difficult to know where to send complaints
- 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.

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Working Group Report



- Working Group on Promotion of Therapeutic Products (to health professionals) delivered its report to Parliamentary Secretary Catherine King on 18 March 2011. Recommended:
 - Alignment of nine Therapeutic Goods Industry Codes via common principles.
 - The government make compliance with a Code a condition of market authorisation (to address the problem of non-members).

The latter was rejected by government!

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The problem of non-members

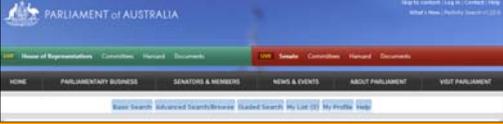


- In 2012, Ranbaxy Australia offered pharmacists A\$14,648 of free Trovas® (generic atorvastatin) stock and a 90% discount for subsequent orders.
- This offer appeared to breach the Code of Conduct of both the Generic Medicines Industry Association (GMiA) and Medicines Australia.
- Ranbaxy Australia Pty Ltd is not a member of any self-regulatory industry association.

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Alternative approach



This bill proposed by Senator R Di Natale would replace the industry code with legislation that sets more stringent restrictions on the interactions between pharmaceutical companies and physicians

Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013

Summary

Progress of bill

Example

<http://www.comlaw.gov.au/Details/C2013B00029/Explanatory%20Memorandum/Text>

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Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013

- Bans payment for *doctors* to travel or attend education seminars and scientific conferences domestically and overseas;
- Bans the sponsorship of educational meetings intended for Australian *doctors* outside Australia;
- Bans gifts and promotional items;
- Limits the amount that could be spent on hospitality (i.e. catering) at information events;
- Requires full reporting on the *corporation's website* (including individual names) of:
 - Advisory board and other consulting fees
 - Speaking fees and travel
 - Any other honoraria or compensation to healthcare professionals.

The Bill has been referred to the Finance and Public Administration Legislation Committee for inquiry and report by 17 June 2013.

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Submissions



Of 24 submissions:

- 18 oppose the bill and supported self-regulation;
- 2 supported the bill;
- 2 pointed out the limitations, both of the bill and self-regulation, and asked for broader debate;
- A late submission from the Department of Health and Ageing reiterated the government's preference for self-regulation but failed to address its limitations.

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Public hearing

Inquiry into the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013

- The AMA publicly embraced transparency.
- Big Pharma also (but no public reporting until 2016).
- Broad agreement (with one exception) that:
 - Transparency should apply to all health professionals and all therapeutic goods companies;
 - Self-regulation needed to be underpinned by appropriate legislation in order to catch non-members of industry associations.
- However, the DoHA / TGA witnesses reiterated the government's aversion to legislation; a new advisory group will assess coverage of self-regulation in 2015-16.

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Self-regulation versus regulation



More health activism required.

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Therapeutic Goods Administration



- 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.

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Therapeutic Goods Administration



- 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 assessed for efficacy.
- Most CMs are listed (AUST L) on the ARTG

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Therapeutic Goods Administration



- The TGA’s electronic listing facility (ELF) allows listed medicines rapid and low cost entry onto the ARTG.
- 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.
- Limited random and targeted post-marketing surveillance is performed.

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Problems with the TGA

- Self-certification by the sponsor of so-called “low-risk” therapeutic goods depends on trust.
- The TGA only performs limited post-marketing reviews of self-certified products. Until recently these results have been regarded as “commercial-in-confidence”.
- A 2009-10 review (of 31 randomly selected complementary medicines) has now been made public by the ANAO. It found:
 - 20 (65%) had labelling issues such as non-compliance with labelling requirements and/or breaches which may mislead consumers.
 - 22 (71%) were found to have manufacturing and/or quality issues.
 - 14 (45%) did not have adequate evidence to substantiate claims made.
- There is no data available on TGA post-marketing reviews of “low-risk” devices.
- Numerous upheld complaints reiterate evidential deficiencies.

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Shonky medicines listed on the ARTG



Xantrax, Fatblaster, Fatblaster Max, Fat Magnet, HungerBuster, SlimRight, Undoit, Sensa...

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Problems with the TGA



- In short, a system based on trust has been shown to fail.
- Removal of products from the ARTG by the TGA for regulatory non-compliance (after protracted due process) does not necessarily stop continued promotion and use.
- In addition, sponsors can readily relist identical products or those with minor changes.
- Unscrupulous sponsors know that the TGA is a paper tiger and the current system can be gamed to their commercial advantage.

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Summary of regulatory problems



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

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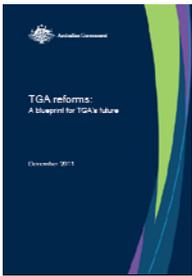
What's been achieved?

- Australian Government. Improving advertising arrangements for therapeutic goods, 2010. <http://www.tga.gov.au/newsroom/consult-advertising-arrangements-101028.htm>
- Australian National Audit Office. Therapeutic Goods Regulation: Complementary Medicines, 2011. <http://www.anao.gov.au/Publications/Audit-Reports/2011-2012/Therapeutic-Goods-Regulation-Complementary-Medicines/Audit-brochure>
- Australian Government. Review to improve transparency of the TGA, 2011. <http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm>
- Australian Government. Working Group on Promotion of Therapeutic Products, 2011. <http://www.health.gov.au/internet/main/publishing.nsf/Content/Consultation:+Position+Paper+on+the+Promotion+of+Therapeutic+Goods>
- Therapeutic Goods Administration, Informal Working Group on Complementary medicines Regulation, 2011-

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What's been achieved?



- Australian Government. TGA reforms: A blueprint for TGA's future, 2011. <http://www.tga.gov.au/about/tga-reforms-blueprint.htm>
- Australian Government. Delivering reforms - Implementation plan for TGA Reforms: A blueprint for TGA's future, 2012. <http://www.tga.gov.au/about/tga-reforms-blueprint-implementation.htm>

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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".
- Distinguish the few properly evaluated Registered complementary medicines from the many that were "grandfathered" into the ARTG.

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What did we want?



- Increased and better targeted post-marketing surveillance and transparent reporting of problems and cancellations.
- Legislation for timely and meaningful sanctions for advertising violations (civil penalties, enforceable undertakings).
- Sponsor's "evidence" on the ARTG web site for evaluation.

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What did we get?

Over 4 years the TGA will:



- Update and include in the regulations the TGA document, *Guidelines for the levels and kinds of evidence to support indications and claims* (two drafts have already been produced)*;
- Amend the Electronic Listing Facility (ELF) to provide increased guidance to sponsors and risk profile information to the TGA (to assist targeted reviews);
- Increase the number of coded indication in ELF to eliminate "creative" use of free text;
- Broaden pre-clearance requirements to include medical devices and advertisements on pay TV (but not the Internet);

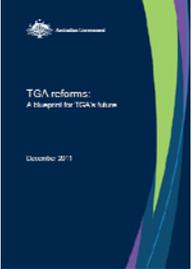
<http://www.tga.gov.au/newsroom/consult-cm-evidence-listed-medicines-120423.htm> 30

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What did we get?

Over 4 years the TGA will:

- Provide more detailed and targeted post-marketing monitoring and reporting by the TGA;
- Create a central point at the TGA for all complaints about advertising, with the TGA to deal with those regarding efficacy or the intended purpose, not the Complaint Resolution Panel;
- Harmonise industry self-regulatory codes of conduct to support consistent ethical standards across the therapeutic goods industry;
- Improve labelling to assist consumers make informed choices;
- Explore enhanced sanctions and penalties for regulatory violations including advertising breaches.



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In conclusion



- Health activists are still needed to:
 - Submit more complaints;
 - Publicise system problems;
 - Put in submissions to industry and government inquiries;
 - Agitate on industry and government working groups.
- Join us!

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