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Self-regulation versus co-regulation: A consumer perspective

Dr Ken Harvey MB BS, FRCPA
http://www.medreach.com.au

ARCS Melbourne Regional Networking Group, April 9, 2013

LA TROBE UNIVERSITY AUSTRALIA

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Talk outline

A fundamental change in the relationship between industry and medical professionals is needed. THE CONVERSATION

- Disclosure of interests;
- Snapshots of current issues;
- Self-regulatory Codes
  - Pros and cons
  - Working group recommendations;
- Current Medicines Australia Code revision
  - Issues raised
  - ACCC authorisation;
- Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013;
- National Medicines Policy.

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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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Snapshots of current issues

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

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World Health Assembly 2007

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.

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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).

1. http://www.tgacrp.com.au/

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Self-regulation: Pros

"The Australian Government's preference is to maintain an emphasis on self-regulation".

TGA reforms: A blueprint for TGA's future. December 2011.

- 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.

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Self-regulation: Cons

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 to know where to send complaints.

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Self-regulation: Cons

- Following media stories about a Sigma cruise and unethical conduct by medical device sponsors Parliamentary Secretary for Health Mark Butler said:
  - "The Government is pursuing a level playing field on marketing obligations within the therapeutic goods industry".

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2010 Working Group on promotion

Anne Trimmer	Medical Technology Association of Australia (Chair)
Anna Lavelle	AusBiotech
Troy Williams	Australian Dental Industry Association
Dr Roderick McRae	Australian Medical Association
Elizabeth Foley	Australian Nursing Federation
Dr Deon Schoombie	Australian Self Medication Industry
Dr Wendy Morrow	Complementary Healthcare Council of Australia
Carol Bennett	Consumers Health Forum of Australia Inc
Kate Lynch	Generic Medicines Industry Association
Dr Peter Harman	IVD Australia
Dr Brendan Shaw	Medicines Australia
Mark Feldschuh	Pharmaceutical Society of Australia
Anne Develin	Pharmacy Guild of Australia
Mary Osborn	Royal Australasian College of Physicians
Dr Ken Harvey	School of Public Health, Latrobe University

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2010 Working Group on promotion

Stakeholder submissions to the Position Paper

The Government received 39 submissions in response to the Position Paper. The submissions that have been approved for publication are below. Note: submissions made by private individuals have had their personal contact details removed.

Promotion Consultation Submission - Assistant Prof Barbara Mintzes (PDF 303 KB)
Promotion Consultation Submission - Assoc Prof Tom Faunce (PDF 260 KB)
Promotion Consultation Submission - AusBiotech (PDF 33 KB)
Promotion Consultation Submission - Australian Skeptics (Victorian Branch) (PDF 60 KB)
Promotion Consultation Submission - Australian Dental Association (PDF 1268 KB) (Large file)
Promotion Consultation Submission - Australian Dental Industry Association (PDF 108 KB)
Promotion Consultation Submission - Australian Nursing Federation (PDF 38 KB)
Promotion Consultation Submission - Australian Orthopaedic Association (PDF 282 KB)
Promotion Consultation Submission - Australian Self Medication Industry (PDF 501 KB) (Large file)
Promotion Consultation Submission - Beverley Snell (PDF 60 KB)
Promotion Consultation Submission - BUKO Pharma-Kampagne (PDF 45 KB)
Promotion Consultation Submission - Chronic Illness Alliance (PDF 21 KB)
Promotion Consultation Submission - Complementary Healthcare Council (PDF 64 KB)
Promotion Consultation Submission - Consumers Health Forum (PDF 333 KB)
Promotion Consultation Submission - Dr Ken Harvey (PDF 454 KB)
Promotion Consultation Submission - Dr Peter Parry (PDF 38 KB)
Promotion Consultation Submission - Generic Medicines Industry Association (PDF 343 KB)
Promotion Consultation Submission - Health Action International Global (PDF 965 KB) (Large file)
Promotion Consultation Submission - Healthy Skepticism (PDF 494 KB)

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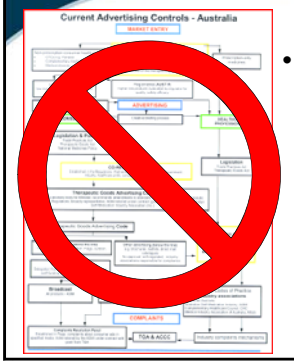
What many advocated



- One Code, one efficient complaint (and appeal) system and one set of effective sanctions applicable to all therapeutic claims and promotional activities regardless of the industry sector, media or target.

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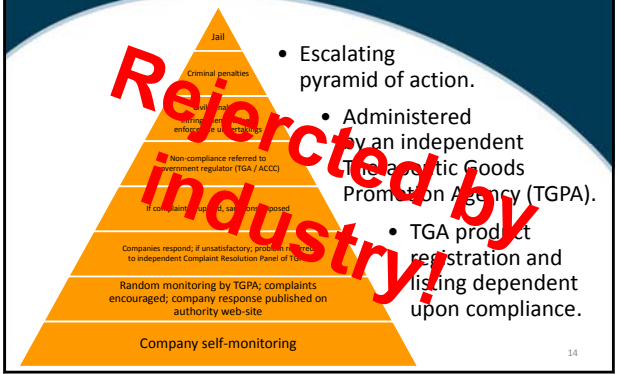
What many advocated



Rejected by industry!

- Escalating pyramid of action.
  - Administered by an independent Therapeutic Goods Promotion Agency (TGPA).
  - TGA product registration and listing dependent upon compliance.

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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.
- High level statement of principle:
  - the Australian therapeutic products industry promotes the concept of good health incorporating the quality use of therapeutic products based on genuine consumer health needs and supported by the ethical conduct of all parties.

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Working Group Report

- The working group recommended that each therapeutic industry sector code address:
  - **Specific operational areas**, such as industry-sponsored educational events, conduct of representatives, hospitality and entertainment, and social media.
  - **Governance areas for the effective implementation:**
    - Education on the code's operation;
    - Monitoring of compliance with the code;
    - Enforcement of the code in response to a complaint or a breach;
    - Sanctions to support the enforcement (at a level that deters non-compliance).

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Working Group Report

- The working group addressed the need for adherence to industry codes by non-members by recommending that all applicants nominate the relevant code of practice to which it will subscribe, as a condition of registration/listing/inclusion of a product on the ARTG.
- The working group notes the Government's intention is for the 'sign on' process to be voluntary in the first instance.
- The working group is concerned that voluntary nomination may not be effective to achieve the Government's objectives and that code nomination should be made a mandatory part of product registration.

Rejected by government!

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2012 Budget measure

- $1.4 million over four years to assist the therapeutic goods industry to develop strong, consistent and enforceable codes of conduct.
- The resources provided through this measure will support implementation of the Working Group's recommendations 4, 9-13 and 15-17, which include:
  - making information on industry codes publicly available, as well as providing access to shared systems for reporting complaints,
  - annually evaluating the effectiveness of voluntary registration to a code of conduct,
  - encouraging health professionals to better align their codes with those of industry,
  - inclusion of education on relationships with therapeutic industry in the training of healthcare professional students.

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Evaluating voluntary Code sign-up

Kate Lynch (CEO, GMiA) noted:

- GMiA already provides an option for non-members to voluntarily sign up to the GMiA Code without joining the association.
- Despite pro-actively advocating this facility no company has taken up the option.
- Non-members have stated that they already adhere to the Code and do not see a need to make any formal declaration.

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Evaluating voluntary Code sign-up

- 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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Evaluating voluntary Code sign-up

Ranbaxy declines GMiA probe

Ranbaxy has told the Generic Medicines Industry Association (GMiA) it will not participate in an investigation of a complaint made over its provision of free Trovas (atorvastatin) stock to some pharmacists.

The offer, made last month, gave pharmacists who had supported Ranbaxy's initial entry into the atorvastatin market close to $15,000 worth of the lipid lowering drug.

Shortly after news of the promotion emerged, well-known drug promotion activist, Key Harvey, complained to the GMiA about it. Although aware that Ranbaxy is not a GMiA member, Dr Harvey said the promotion was "bringing discredit to the sponsors of generic medicines".

In a letter to Dr Harvey, GMiA CEO, Kate Lynch said, "On 18 May GMiA forwarded your letter to Ranbaxy offering Ranbaxy the option to have the complaint adjudicated by the GMiA Code Complaint Committee. GMiA advises that Ranbaxy has declined the GMiA's offer."

Ranbaxy Managing Director, Alex Evans, said, "Ranbaxy Australia has declined the GMiA's offer to have the GMiA Code Complaint Committee adjudicate a complaint made to the GMiA by Dr Harvey. Ranbaxy Australia is confident that its conduct in this matter is in accordance with applicable laws and the marketing authorisation for Trovas." **NL**

http://www.pharmainfocus.com.au/news.asp?newsid=5482

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Evaluating voluntary Code sign-up

- Media Watch (April 1, 2013)
  - Gerald Quigley: ... there's lots of different brands, David, but the one I use comes from Sydney, it's called Bloom's Wild Red krill oil....
    - *— Radio 6PR, Afternoons with Rod Tiley, 18th January, 2013*
  - Gerald Quigley: ... a turmeric based anti-inflammatory called Nagesic Forte which is much more effective than Panadol Osteo, get them from your pharmacy
    - *— Radio 3AW, Afternoons with Denis Walter, 21st January, 2013*

- Again and again Mr Quigley plugs the products of companies for whom he consults, without disclosing the relationship. Although we asked him twice, Mr Quigley's declined to say whether he's actually paid to spruik their wares: http://www.abc.net.au/mediawatch/transcripts/s3727489.htm.

17th Edition of Medicines Australia Code

Submissions to 2011/2012 Code Review

- Amgen 410k
- AstraZeneca 107k
- Atlantis Healthcare 79k
- Australia and New Zealand Bone and Mineral Society 21k
- Australian Medical Association 84k
- Australian Society of Anaesthetists 40k
- Baxter Healthcare 28k
- Brand Promotions 197k
- Centre for Health Initiatives, The University of Wollongong 351k
- Consumers Health Forum 238k
- Council of Australian Therapeutic Advisory Groups 346k
- CSL 176k
- Department of Health, ACT 25k
- Department of Health, NSW 131k
- Department of Health, South Australia 407k
- Department of Health, Victoria 80k
- Department of Health, Western Australia 161k
- Dr Agnes Vitry 134k
- Dr Ken Harvey 186k

Report of Consumer Workshops on the Medicines Australia Code of Conduct

Written by Ann Porcino, RPR Consulting
16 April 2012

RPR CONSULTING

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Issues raised

- Should the industry continue to be self-regulated?
- Applicability to non-members?
- Who sets the standards?
- Specific concerns?
  - *Disclosure of relationships with healthcare professionals and community organisations,*
  - *Product specific media releases,*
  - *Starter Packs, Product Familiarisation Programs, Disease Awareness Advertising,*
  - *Patient Support Programs,*
  - *Sanctions and monitoring,*
  - *Marketing the Code to the general public.*

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Who sets the standards?

- Industry Codes tend to be more effective when the self-regulatory body comprises representatives of the key stakeholders, including consumers, consumer associations, the government and other community groups.

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Disclosure of financial relationships

- New code incorporates further disclosure of payments to health care professionals (HCP) in the form of an aggregate report for payments.
- MA was cognisant of the desire to disclose names within the report, but felt that broader engagement of the HCP community was needed before implementation.
- MA planed to have these discussions over the next few years in order to reach an agreement on this disclosure.
- This falls far short of the full disclosure of payments made to individual healthcare professionals which many consumer and health professional groups have argued for both in the 16th Edition (2009) Code revision and again in the 17th Edition (2012) Code revision

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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 collection starting January I, 2013.

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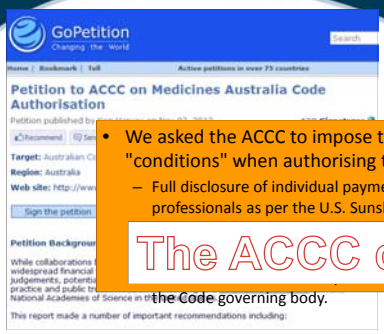
ACCC Code authorisation



- We asked the ACCC to impose the following "conditions" when authorising the Code:
  - Full disclosure of individual payments to healthcare professionals as per the U.S. Sunshine Act.

The ACCC declined

the Code governing body.

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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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Other issues raised

- Should the industry continue to be self-regulated?
- Who sets the standards?
- Applicability to non-members?
- Specific concerns?
  - *Disclosure of relationships with healthcare professionals and community organisations,*
  - *Product specific media releases,*
  - *Starter Packs, Product Familiarisation Programs, Disease Awareness Advertising,*
  - *Patient Support Programs,*
  - *Sanctions,*
  - *Marketing the Code to the general public.*

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Product specific media releases

This press release resulted in a 7 minute radio interview with one of the "Leading" doctors below in which the drug brand name (***Actonel® EC***) was mentioned 15 times

Is a $40,000 fine a real deterrent for a multi-national drug company?

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Are current sanctions effective?

- 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 5 years settlements for criminal and civil monetary penalties from the U.S. pharmaceutical industry reached a total of $15 billion.

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Conduct leading to the U.S. fines

- 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.
- Consumer groups manipulated.
- Spurious patents and legal challenges to delay the entry of generics.

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It takes two to tango

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It takes two to tango

pharma phacts

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It takes two to tango

The Pharma Phacts Pledge

I pledge to accept no money, gifts, or hospitality from the pharmaceutical industry; to seek unbiased sources of information and not rely on information disseminated by drug companies; and to avoid conflicts of interest in my medical education and practice.

http://healthyskepticism.org/pharmaphacts/index.php

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Dos and don'ts of industry collaboration 2012

Reality Check: Ray Moynihan
http://www.bmj.com/content/344/bmj.e3247

http://www.abpi.org.uk/our-work/library/guidelines/Documents/Guidance%20on%20collaboration.pdf

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So, how do we know if self-regulation is working?

- Effective codes require collection of data to be analysed to produce reports that highlight any systemic issues and areas for potential improvement.
- The committee should also produce annual reports on the operation of the code, allowing for periodic assessment of its effectiveness. These reports should be readily available to all stakeholders and interested parties

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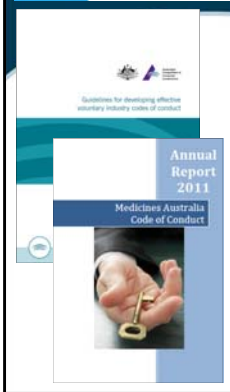
So, how do we know if self-regulation is working?



- Less complaints?
  - Complaint fatigue?
  - Defamation actions discourage complainants?
  - No U.S. False Claims Act to encourage whistle-blowers (15%-30% reward).
- Monitoring committee reports a high level of Code compliance from random reviews of material?
  - Educational event reporting does not clarify which events have company sponsored speakers compared to independent ones.
  - But the activities of pharmaceutical representatives are not monitored.

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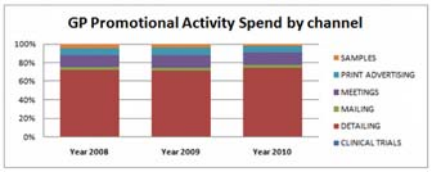
Australian GP promotional spend 2010

PROMOTION SPEND - AUSTRALIAN GPs			
	324,842,602	321,595,965	[illegible]
Channels	Year 2008	Year 2009	Year 2010
CLINICAL TRIALS	920,809	892,216	[illegible]
DETAILING	232,647,568	226,816,872	[illegible]
MAILING	8,664,651	10,137,690	[illegible]
MEETINGS	42,804,971	43,645,323	[illegible]
PRINT ADVERTISING	26,044,943	27,159,976	[illegible]
SAMPLES	13,759,659	12,943,888	[illegible]

Cegedim Strategic Data



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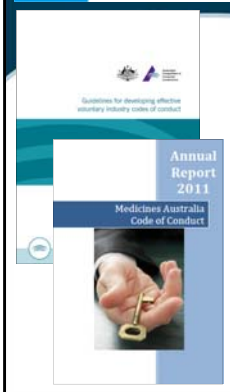
So, how do we know if self-regulation is working?



- Continuing Educational Program for pharmaceutical representatives is mandated?
  - But in Australia bonuses are paid for increased sales.
  - GSK Corporate Integrity Agreement states:
    - GSK agrees that it will not provide financial reward or discipline its pharmaceutical sales representatives or their direct managers based upon the volume of sales.
- Annual reports are produced?
  - But reports (in PDF) cannot be readily analysed to track non-compliance by company over time.

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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

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. Submissions should be lodged by 19 April 2013.

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Australian Medicines Policy

1. Medicines of high quality, safety
2. Equitable & timely access to necessary
3. Quality use of medicines
4. responsible local pharmaceutical industry

Balancing these four objectives depends upon active and respectful partnerships between all stakeholders

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Further reading

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- Australian Government. Delivering reforms – Implementation plan for TGA Reforms: A blueprint for TGA's future, July 2012. http://www.tga.gov.au/about/tga-reforms-blueprint-implementation.htm
- Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and GlaxoSmithKline LLC. http://oig.hhs.gov/fraud/cia/agreements/GlaxoSmithKline_LLC_06282012.pdf

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