Self-regulation versus co-regulation: A consumer perspective

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ARCS Melbourne Regional Networking Group, April 9, 2013

Talk outline
- 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.

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.
  - Government Natural Therapy Review Advisory Committee.

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)

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.

What about Australia?

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

- Self-regulation (promotion to health professionals)
  - Industry Codes and complaints panels in nine sectors: Medicines Australia, GMIA, ASMHI, CHC, MTAA, AudBioTech, IVD Australia, ADA, ACCORD.
- Co-regulation (promotion to consumers)
  - Therapeutic Goods Advertising Code (TGAC), Complaints Resolution Panel (CRP) and TGA.
- Regulation (legislation)
ARCS Melbourne Group

Self-regulation versus co-regulation

Self-regulation: Pros

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

The Australian Medical Association
Dr. Ken Harvey
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• 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

• 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.

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 pursing a level playing field on marketing obligations within the therapeutic goods industry".

2010 Working Group on promotion

2010 Working Group on promotion

Anne Trimmer Medical Technology Association of Australia (Chair)
Anna Lavelle AusBiotech
Troy Williams Australian Dental Industry Association
Dr. Roberta Milley Australian Medical Association
Elizabeth Foley Australian Nursing Federation
Dr. Dean Schonfeld Australian Self Medication Industry
Dr. Wendy Morrow Complementary Healthcare Council of Australia
Carol Bennett Consumer Health Forum of Australia Inc.
Kate Lynch Generic Medicines Industry Association
Dr. Peter Harman SYA Australia
Dr. Brendan Shear Medicines Australia
Mark Fieldschuk Pharmaceutical Society of Australia
Anna Devlin Pharmacy Guild of Australia
Mary Osborn Royal Australian College of Physicians
Dr. Ken Harvey School of Public Health, Latrobe University

Micronisole submissions to the Positive Paper

The Government invites 13 submissions in response to the Positive Paper. The submissions that have been approved for publication and below. Note: submissions may be made to the public if they have personal or trade secrets removed.

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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.

What many advocated

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

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.

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).

Working Group Report

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

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.
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.

- In 2012, Ranbaxy Australia offered pharmacists $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.

- 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...
  - 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.

- 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.
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.

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 planned to have these discussions over the next few years in order to reach an agreement on this disclosure.

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 1, 2013.

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.

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.)

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,
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  - Patient Support Programs,
  - Sanctions,
  - Marketing the Code to the general public.
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?

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.

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.

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
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.

Dos and don’ts of industry collaboration 2012

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

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.

Australian GP promotional spend 2010

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

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

Further reading

- BMJ on Doctors, patients, & the pharmaceutical industry, February 2009:
  http://www.bmj.com/content/339/bmj.e3974
- Royal College of Physicians. Innovating for health, February 2009:
  http://www.rcplondon.ac.uk/research/pharmaceuticals-and-medicine
- Moynihan RN. Kissing goodbye to key opinion leaders. MJA 2012; 196: 671.
- Gale EAM. Post-marketing studies of new insulins: sales or science. BMJ 2012, 344:e3974 doi 10.1136/bmj.e3974

Further reading

- Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and GlaxoSmithKline LLC.