Sydney Seminar, March 17, 2016
Advertising of Therapeutic Goods and Services (and its Regulation)

Background Paper

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Introduction

This seminar is to be held back-to-back with World Consumer Rights Day 2016 (March 15) and the National Consumer Congress (March 16).[1] The latter is hosted by the Australian Competition and Consumer Commission (ACCC).[2] The 2016 Congress will discuss how to better protect and empower consumers in the lead up to the review of the Australian Consumer Law.

Our seminar's aim is to outline current concerns that consumer (and health professional) organisations have with the advertising of therapeutic goods and services and explore ways in which the system(s) might be improved.

Organisations that have expressed concern about these matters include the Consumers Health Forum, Choice (Australian Consumers' Association), Friends of Science in Medicine, Australian Skeptics, the Doctors Reform Society and Stop the Australian (Anti) Vaccination Network.

The seminar is organised and supported by Choice,[3] the Foundation for Effective Markets and Governance (FEMAG),[4] University of Sydney (Health Law Centre),[5] Monash University (School of Public Health and Preventative Medicine)[6] and the ACCC.

Topics to be discussed

The promotion of therapeutic goods to health professionals: Industry self-regulatory codes

The promotion of therapeutic goods to health professionals is governed by industry self-regulatory codes. For example, Medicines Australia self-regulatory code and complaint system deals with promotion of prescription pharmaceuticals to health professionals. It's efficient, effective, transparent and applies a range of sanctions including fines and retractions.[7] It recognises that complaints may just be the tip of the iceberg and so includes a monitoring system which regularly reviews various types of promotion.

Medicines Australia code been improved over the years, both by public input and the ACCC imposing conditions on its authorisation.[8] Regardless, the latest code is not without its critics.[9] In addition, although promotion of prescription products to consumers is not allowed, there is concern that some activities, such as Product Familiarisation Programs and Patient Support Programs push the boundaries.

More importantly, Medicines Australia code only applies to its own members; other industry associations have less rigorous codes, while non-members of therapeutic goods industry associations are not covered at all. Several industry associations have now declined to submit their codes to the ACCC for authorisation, thus escaping the ACCC persuasive abilities. More recently, the Generics Medicines Industry Association (now rebranded as GBMA), has decided to cease their reporting of non-price benefits and educational events.

In 2011, a government working party made recommendations for aligning self-regulatory therapeutic goods industry codes and making compliance with them a condition of marketing

[1] https://consultation.accc.gov.au/consumer-small-business/ruby-hutchison-national-consumer-congress
[2] https://www.accc.gov.au/
[3] https://www.choice.com.au/
[4] http://femag.org.au/
[5] http://sydney.edu.au/law/health/
[6] http://www.med.monash.edu.au/sphpm/
[7] https://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-reports/
[8] https://www.accc.gov.au/media-release/accc-authorises-medicines-australia-code-subject-to-strengthening-individual-reporting
[9] https://croakey.org/inside-the-fight-for-greater-transparency-around-pharma-payments-to-doctors/

authorisation by the Therapeutic Goods Administration.[10] Regrettably, an Implementation Advisory Group set up by the former government has not been progressed by the current government.[11]

A Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill (2013) was proposed by Senator Richard Di Natale to create offences related to the provision of payments, services or certain other inducements to medical practitioners by pharmaceutical companies. This did not proceed due to the government's preference for self-regulation.[12]

The promotion of therapeutic goods to consumers

The *Therapeutic Goods Act 1989* and *Regulations 1990* created a Therapeutic Goods Advertising Code (based on the WHO Ethical Criteria for Medicinal Drug Promotion), a Code Council and a Complaint Resolution Panel (CRP). In addition, there are industry codes of practice. Limited pre-clearance of print and television (but not Internet) advertisements is delegated to industry associations. The Therapeutic Goods Administration (TGA) has overall responsibility for the successful operation of the system and provides information both on advertising requirements and the various places complaints can be sent, which includes itself.[13]

The CRP receives, considers and determines complaints about advertisements directed to consumers in TV, radio, the internet, newspapers, magazines, displays (except inside individual shops) and cinematographic film. Complaints about advertisements directed to consumers in all other media (e.g. leaflets, brochures, catalogues, shelf talkers) are addressed by industry self-regulatory associations. The CRP offers a central complaints mailbox and sends complaints that do not fall within its jurisdiction to the most appropriate authority. For example, a complaint about the advertising of a product that had not been entered into the Australian Register of Therapeutic Goods (ARTG)[14] would be sent to the TGA.

The CRP makes public its determination of complaints[15] but other authorities are not so transparent. Unfortunately, the CRP has no power to enforce its determinations. As a result, non-compliance is common. These cases are then passed to the TGA who, after a review of the case (usually delayed) may issue a Regulation 9 order for compliance.[16] Once again this can be ignored &/or the process delayed by appeals to the Minister, the Administrative Appeals Tribunal, &/or withdrawing the product from the market and re-listing an identical one with similar claims.

Not surprisingly, recommendation 56, from the recent Stage 2 Report from the Review of Medicines and Medical Devices Regulation stated that the entire CRP / TGA system of handling complaints should be revamped.[17]

The food-medicine interface is another problem.[18,19] Increasingly, a number of products (especially those used for body-building and weight loss) are classified as foods to take advantage of the regulatory confusion over who is responsible for products bridging the food-medicine interface.[20]

The ACCC has become involved in the promotion of therapeutic goods to consumers when product sponsors are intransigent &/or the case involves important issues of consumer protection. Recent

[10] http://www.health.gov.au/internet/main/publishing.nsf/Content/RPGD-Promotion-of-Therapeutic-Goods
[11] http://www.health.gov.au/internet/main/publishing.nsf/Content/RPGD-Promotion-of-Therapeutic-Goods-Codes-of-Conduct-ToR
[12] http://tinyurl.com/hatagv4
[13] https://www.tga.gov.au/regulation-therapeutic-goods-advertising-australia
[14] https://www.tga.gov.au/australian-register-therapeutic-goods
[15] http://www.tgacrp.com.au/index.cfm?pageID=13
[16] https://www.tga.gov.au/decisions-relation-complaints-about-advertisements-sorted-date
[17] http://www.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation
[18] https://theconversation.com/regulations-around-food-medicine-products-fail-to-protect-consumers-14360
[19] http://www.abc.net.au/news/2016-03-01/supplements-linked-to-at-least-6-australian-organ-transplants/7207472
[20] https://www.tga.gov.au/community-qa/food-and-medicine-regulation

examples include Sensaslim,[21] Homeopathy Plus,[22] Nurofen,[23] and Breast Check.[24] Mr Rod Sims (ACCC Chair) has noted consumer issues in the health and medical sector remain a priority in 2016.[25]

Unlike the TGA, the ACCC has both the culture and teeth to pursue deceptive claims and is at arm's length from the therapeutic goods industry. It has been suggested that one option for revamping the complaint system would be reconstituting an expanded CRP under the auspices of the ACCC (and National Consumer Law). The CRP would then become a one-stop-shop for all complaints about the promotion of therapeutic goods to consumers and would triage worked up complaints to the ACCC, TGA, FSANZ, State Health Departments and industry associations as appropriate. It would also be responsible for maintaining a master public complaint register, distilling key educational messages and commissioning monitoring of advertising.

Promotion of therapeutic services by registered health professionals

The Australian Health Practitioner Regulation Agency (AHPRA) was set up by the Health Practitioner Regulation National Law (the National Law), in force in each state and territory which came into effect on 1 July 2010. [26] This law means that for the first time in Australia, 14 health professions are regulated by nationally consistent legislation under the National Registration and Accreditation Scheme (NRAS).

AHPRA supports the 14 National Boards that are responsible for regulating the health professions. The primary role of the National Boards is to protect the public; they set standards and policies that all registered health practitioners must meet. Each Board has entered into a health profession agreement with AHPRA which sets out the fees payable by health practitioners, the annual budget of the Board and the services provided by AHPRA.

The Agency Management Committee oversees the work of AHPRA. The Chair is Mr Michael Gorton AM. AHPRA is responsible to the COAG Health Council, currently Chaired by the South Australian Health Minister, Jack Snelling.[27]

The 2015 Independent Review of NRAS noted significant achievements in the five years since it had been established.[28] However, it also highlighted the need for AHPRA to respond more effectively to complaints about registered health professionals. The latter issue has attracted considerable media attention of late because of concern that AHPRA and the Chiropractic Board have failed to protect the public from unlawful advertising by chiropractors and that their complaint procedures are non-transparent, inefficient and ineffective.[29]

For example, despite hundreds of complaints, submitted over many years, AHPRA and the Chiropractic Board have never published specific determinations about these complaints. Public complaint determinations would inform practitioners and consumers what claims were, or were not, judged in breach of s.133 of the National Law. Instead, until very recently the Chiropractic Board has merely repeatedly expressed concern that practitioners may be in breach of advertising requirements, urged them to obey the National Law and practice in an evidence-based manner.[30]

On March 7, 2016 the Chiropractic Board issued a media release and a statement on advertising that, for the first time, named some common advertising claims the Board believed lacked sufficient evidence to justify them.[31] The Board strongly encouraged practitioners to review their advertising

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[21] https://www.accc.gov.au/media-release/court-finds-sensaslim-misled-franchisees-about-peter-fosters-involvement
[22] http://www.accc.gov.au/media-release/court-finds-homeopathy-plus-vaccine-claims-misleading
[23] http://www.accc.gov.au/media-release/court-finds-nurofen-made-misleading-specific-pain-claims
[24] http://www.accc.gov.au/media-release/court-finds-breast-imaging-provider-engaged-in-misleading-conduct
[25] http://www.accc.gov.au/speech/accc-compliance-and-enforcement-priorities-for-2016
[26] http://www.ahpra.gov.au/About-AHPRA/Who-We-Are.aspx
[27] http://www.coaghealthcouncil.gov.au/
[28] http://www.coaghealthcouncil.gov.au/Publications/Reports/ArtMID/514/ArticleID/68/The-Independent-Review-of-the-National-Registration-and-Accreditation-Scheme-for-health-professionals
[29] http://www.medreach.com.au/?p=1464
[30] http://tinyurl.com/js6dm3q
[31] http://www.chiropracticboard.gov.au/News/2016-03-07-statement-on-advertising.aspx

to ensure it complied with the requirements of the National Law; otherwise they risked prosecution and/or disciplinary action. It remains to be seen what effect this more specific statement will have.

It's been said that AHPRA is "an expensive experiment" that has partially failed; that its powers to investigate complaints about registered practitioners should be handed back to the States, and a much reduced AHPRA should simply maintain the national registration database.[32]

Less radically, it has been suggested that AHPRA should publish specific determinations about each complaint received, noting what claims did, or did not, breach the National Law. In addition, AHPRA should use Part 7, of the National Law to prosecute advertising offenders in the Magistrates Court (maximum penalties available for this statutory offence are $5 000 for an individual and $10 000 for a body corporate). Part 8 of the National Law should be used to sanction recalcitrant practitioners for repeated advertising offences. Penalties available under Part 8 include cautions, accepting undertakings, placing conditions of the practitioner's registration or, for professional misconduct, referral to a tribunal with the power to impose additional penalties, including a fine of up to $30 000. Another advantage of using Part 7 and 8 of the National Law is that Court and Tribunal Decisions about individual practitioners are published on the AHPRA web site.

Finally, it should be noted that non-evidenced based practice is not restricted to chiropractors; other Boards are grappling with similar issues.[33]

Promotion of therapeutic services by unregistered health professionals

National registration of health professions by AHPRA aims to ensure a minimal level of education and training, appropriate standards of professional behaviour and effective and efficient complaint mechanisms.

Naturopaths and many other complementary medicine (CM) practitioners have not achieved national registration, in part because of division in their ranks, but also because of their varied training. CM practitioners may be members of professional associations (which are numerous) but this does not necessarily ensure evidence-based practice, continuing professional education or good complaint handling processes.

State based health complaints entities and/or the ACCC are available for complaints about unregistered practitioners but they have problems, for example a practitioner sanctioned in one State may simply move to another.

In 2011 the Australian Health Ministers' Advisory Council (AHMAC) released a consultation paper on, "Options for regulation of unregistered health practitioners" and in 2015 the final, "National Code of Conduct for health care workers" was released.[34] Clause 9 (c) of the Code states: "a health care worker must not make claims either directly to clients or in advertising or promotional materials about the efficacy of treatment or services he or she provides if those claims cannot be substantiated".

It was recommended that:

- the "National Code of Conduct for health care workers" be the basis for enactment of a nationally consistent code-regulation regime for all health care workers.
- jurisdictions enact or amend legislation to give effect to the National Code of Conduct and a nationally consistent code-regulation regime for health care workers.
- an independent review of the national code-regulation regime be initiated by Health Ministers following five years of the regime's operation or an earlier review if requested by Health Ministers.

While Victoria has recently introduced appropriate legislation,[35] it remains for all State and Territory jurisdictions to progress legislative changes to give effect to the National Code. In addition, a lead

[32] http://www.publish.csiro.au/paper/AH15187.htm
[33] http://www.theage.com.au/victoria/camberwell-gp-geoff-kemp-fighting-for-his-medical-licence-20160301-gn7lzk.html
[34] http://tinyurl.com/h9y5ddr
[35] http://www.premier.vic.gov.au/new-laws-to-crack-down-on-dodgy-health-providers/

jurisdiction is still to be determined to administer a national register of prohibition orders; develop and maintain explanatory materials and establish a common framework for data collection and performance reporting. More action is required.

Past history

The history, reviews and consultations on the promotion of therapeutic goods and services are tabulated in Appendix I and II. While many useful (and repeated) recommendations have been made over the years there has been limited implementation, in particular, we still lack timely and effective penalties for violations of the Therapeutic Goods Advertising Code.

The reasons for this procrastination are varied, ranging from changing bureaucrats, changing Ministers, changing governments and changing policies; the most recent of which has been the current government's, "cutting red tape" agenda which pre-empted the TGA's 2013 "Regulation Impact Statement: Regulating the advertising of therapeutic goods to the general public" with a new "Expert Review of Medicines and Medical Devices Regulation".[36]

Some possible recommendations for government that could be considered by seminar participants are listed in Appendix III.

[36] http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2014-dutton091.htm

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Appendix I. History, reviews and consultations on the promotion of therapeutic goods

Date	Initiative
1997	• Amendments to Therapeutic Goods Act 1989 established the Therapeutic Goods Advertising Code, the Therapeutic Goods Advertising Code Council and the Complaints Resolution Panel
1999	• Major review of advertising arrangements established principles-based code and expansion of approval and complaints processes to additional forms of therapeutic goods advertising
2002	• Proposal for a Trans Tasman Agency to Regulate Therapeutic Products (TGA/Medsafe) • Report of a Review of Advertising Therapeutic Products in Australia and New Zealand
2003	• Therapeutic Goods Amendment Act 2003, amended legislation relating to advertising • Report of Expert Committee on Complementary Medicines in the Health System
2005	• Description of the joint (Trans-Tasman) regulatory scheme for the advertising of therapeutic products
2006	• Consultation (Draft) Regulation Impact Statement on the proposed amendments to the current regulatory system for herbal and homoeopathic medicines in Australia
2007	• Consultation draft (Trans-Tasman) advertising rule
2008	• Regulation of homoeopathic and anthroposophic medicines in Australia
2009	• Draft Guideline for Levels and Kinds of Evidence for Listed Medicines with Indications and Claims for Weight Loss
2010	• TGA Consultation: Improving advertising arrangements for therapeutic goods
2011	• Consultation and Report of the Working Group on Promotion of Therapeutic Products • Report of the Review to improve the transparency of the Therapeutic Goods Administration • ANAO Report. Therapeutic Goods Regulation: Complementary Medicines • TGA reforms: A blueprint for TGA's future
2012	• Delivering reforms - Implementation plan for TGA Reforms • TGA Advertising regulatory framework: Options for reform
2013	• TGA Consultation Regulation Impact Statement: Regulating the advertising of therapeutic goods to the general public
2014	• Expert Review of Medicines and Medical Devices Regulation (Government de-regulation agenda) • Australian and New Zealand Governments agreed to cease efforts to establish a joint therapeutic products regulator
2015	• Expert Review of Medicines and Medical Devices Regulation: recommendations and stakeholder forum

Appendix II. Reviews and consultations on the promotion of therapeutic services

Date	Initiative
2006	• Council of Australian Governments (COAG) agrees to establish a single national registration scheme for health professionals
2008	• COAG members sign Intergovernmental Agreement to establish National Scheme
2009	• Consultation on the National Scheme with stakeholders
2010	• Ministerial Council approves mandatory registration standards developed by National Boards • National Law and the National Scheme begin, National Boards start regulating 10 professions, AHPRA begins operations, 500,000 health practitioners transfer to national registers
2011	• AHPRA and National Boards release National Registration and Accreditation Scheme Strategy • National public consultation on options for the regulation of unregistered health practitioners (AHMAC)
2013	• AHMAC agreed in principle for a single national Code of Conduct for unregistered health practitioners
2014	• Second national public consultation on proposed National Code (AHMAC)
2015	• Report of the independent three-year review of the National Registration and Accreditation Scheme released and COAG Health Council responds. • COAG Final Report, A National Code of Conduct for (unregistered) health care workers

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Appendix III. Possible recommendation to government (for debate).

Issue	Recommendation
AHPRA	• Publish specific complaint determinations about what advertising claims of practitioners were, or were not, judged to breach the National Law as an educative measure. • Use Part 7, subdivision 4, s.133 of the National Law to prosecute advertising offenders in the Magistrates Court; maximum penalties available for this statutory offence are $5 000 for an individual and $10 000 for a body corporate. • Use Part 8 of the National Law to sanction recalcitrant practitioners for repeated advertising offences. Penalties available include cautions, accepting undertakings, placing conditions of the practitioner's registration or, for professional misconduct, referral to a tribunal with the power to impose additional penalties, including a fine of up to $30 000. • Court and Tribunal Decisions about individual practitioners are published on the AHPRA web site
Unregistered practitioners	• COAG Health Council to nominate a lead jurisdiction to administer a national register of prohibition orders; develop and maintain explanatory materials and establish a common framework for data collection and performance reporting.
Industry self-regulation	• Federal government to resurrect the Implementation Advisory Group in order to achieve uniform Codes of Conduct and make compliance with them a condition of marketing authorisation by the TGA by legislation or regulation.
Promoting therapeutic goods to consumers	• Reconstitute an expanded CRP under the auspices of the ACCC (and National Consumer Law); • Make it a one-stop-shop for all complaints about the promotion of therapeutic goods to consumers; • Let it triage worked up complaints to the ACCC, TGA, FSANZ, State Health Departments and industry associations as appropriate; • Make it responsible for maintaining a master complaint register, distilling key educational messages and commissioning occasional monitoring of advertising (as complaints are just the tip of the iceberg).