28 July 2009

LA TROBE UNIVERSITY

School of Public Health
Faculty of Health Sciences

Dr Richard Chadwick
General Manager
Adjudication Branch
Australian Competition &
Consumer Commission
GPO Box 3131
Canberra, ACT, 2601

Dear Dr Chadwick,

Re: Medicines Australia Code reauthorisation (A91150) and anti-competitive codes

I am responding to your written request to provide a submission on this matter dated July 7, 2009.

I believe that Medicines Australia deserve congratulation for making further incremental improvements to the 16th edition of their Code. In particular, I and others have argued for some time that pharmaceutical promotion should not be allowed in prescribing software;[1] it was gratifying to see that this was finally accepted. A number of submissions to the Code review also argued that fines for Code offences should be substantially increased on the grounds that existing sanctions do not appear to deter repeated Code offences. The end result was only a modest increase in the fines allowed; this is one area where the ACCC might consider whether a minor variation of the Code is warranted.

However, my main concern is that the continued improvement of Medicines Australia's Code has now resulted in an anti-competitive environment with respect to different sections of the Australian medicines industry: prescription products (innovator compared to generic), compared to over-the-counter and complementary medicines.

This problem was highlighted recently by a complaint I submitted to Medicines Australia about Sigma Pharmaceuticals Limited. Sigma had promoted a 10-day luxury Mediterranean cruise for doctors and pharmacists with around one and a half days educational content (and 3-4 Sigma drug representatives on-board for the duration). My complaint alleged that this event appeared to breach a number of provisions of Medicines Australia Code; most obviously section 6.6 (venue of educational events). However, Sigma, not being a member of Medicines Australia, declined to have the complaint heard by Medicines Australia.

I had understood from the web site of the Therapeutic Goods Administration (TGA) that their letter of marketing approval required that the promotion of all prescription products (whether member or non-member) comply with the requirements of the Medicines Australia Code of Conduct.[2] In addition, the *Therapeutic Goods Act 1989* notes that advertisement, in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods. I had argued that the purpose of the advertisement promoting the Sigma cruise (and the cruise itself) was clearly to promote the use and supply of their products.

However, the TGA informed me[3] that the actual wording of their letter of marketing approval

1 Harvey KJ, Vitry AI, Roughead E, et al. Pharmaceutical advertising in prescribing software: an analysis. MJA 2005; 183: 75-79. http://www.mja.com.au/public/issues/183_02_180705/har10263_fm.html
2 http://www.tga.gov.au/docs/html/advreg.htm
3 Email from Kay.McNiece@health.gov.au, Re: Sigma Mediterranean Conference for GPs and Pharmacists [No Protective Marking] [SEC=UNCLASSIFIED] Date: Tue, 14 Jul 2009 11:15:32 +1000

states that,

> "promotional material... relating to the registered good must comply with the requirements of the Code of Conduct of Medicines Australia".

They have interpreted that statement to mean that,

> "There is no condition that other promotional activities must comply with the Medicines Australia Code of Conduct".

The end result of this TGA interpretation is a higher standard of ethical conduct expected for innovator compared with generic companies. The Sigma case is just one example of anti-competitive inconsistencies between various systems aimed at controling unethical promotional practices.

Currently, Australia has a variety of complex and convoluted co-regulatory systems to control unethical therapeutic claims and promotional practices depending upon the type of product (innovator and generic prescription, over-the-counter and complementary medicines, therapeutic devices, food and cosmetics) and the media in which claims are made.[4] There are different standards and gross inconsistencies between various Codes of Conduct, their complaint processes, timeliness, transparency, sanctions, monitoring and effectiveness.[5,6,7]

For example, complaints about the promotion of listed products (most complementary medicines) go either to the Complaint Resolution Panel (CRP) if published in mainstream media (including the Internet) or to the Complaint Resolution Committee (CRC) of the Complementary Health Care Council of Australia (CHC) if in other media. Many campaigns involve both.

The CRP publishes details of its determinations on its web site[8] but lacks enforcement power; as a result their "requests" to sponsors are often ignored. If this is brought to the attention of the CRP the matter may be referred to the TGA where it invariably disappears.

The CRC publishes no details of complaints received or any determinations made; they only provide summary statistics in annual reports,[9] including the number of complaints referred to the TGA (who again provide no information on what, if anything, was done).

The end result is that complaints referred to the TGA have no public record of their outcome, the deterrent effect of publicity is lost and complainants become disillusioned with the process. In addition, claims judged to be unsubstantiated by authorised complaint handling bodies continue to be promoted in the marketplace, presumably because of TGA inaction.

I believe that it is time the above complexity was simplified and unified by creating one Code applicable to all therapeutic claims and promotional practice; one complaint (and appeal) process, one monitoring process and one set of effective sanctions, including corrective advertising orders and fines related to the sales income of the product and company involved. The process should be overseen by government, funded by industry (using a moiety of product registration fees), and administered by an independent committee representative of all stakeholders. The system should have a legislative base in the Therapeutic Goods Act and/or

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4 Complaints about advertisements for therapeutic products in Australia: http://www.tgacrp.com.au/index.cfm

5 Harvey KJ, Korczak VS, Marron LJ, Newgreen DB. Commercialism, choice and consumer protection: regulation of complementary medicines in Australia. MJA 2008; 188 (1): 21-25. http://www.mja.com.au/public/issues/188_01_070108/har10522_fm.html

6 http://www.crikey.com.au/2008/07/30/regulation-of-complementary-medicine-marketing-is-a-joke/

7 Harvey K. A review of proposals to reform the regulation of complementary medicines. Aust Health Rev 2009: 33(2); 279-285. http://www.aushealthreview.com.au/publications/articles/issues/ahr_33_2_0509/ahr_33_2_279.html

8 http://www.tgacrp.com.au/index.cfm?pageID=13

9 http://www.chc.org.au/News/AnnualReport/

regulations and be capable of being enforced. South African legislation provides a model of such a broader system (involving all types of medicines).[10]

In May 2007, Australia (and other member states) adopted World Health Assembly Resolution WHA 60.16.5 on Rational Use of Medicines. This urged member states to,

> "Enact new, or enforce existing, legislation to ban inaccurate, misleading or unethical promotion of medicines, to monitor promotion of medicines, and to develop and implement programmes that will provide independent, non-promotional information about medicines".

I should be grateful for the response of the ACCC to this proposal which, I believe, would be a practical demonstration of Australian commitment to WHA Resolution 60.16.5. Equally important, this proposal would provide a level playing field for all sponsors of therapeutic goods as distinct from the current anti-competitive environment.

Finally, because the matters discussed above are much wider than the call for comment about Medicines Australia Code reauthorisation, I have copied this communication to the ACCC Chairman.

Yours sincerely,

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cc

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10 http://www.piasa.co.za/assets/attachments/SACode_for_Marketing_Medicines_080129.pdf

Hospitals win reprieve from takeover

BY PAUL SMITH AND AAP

PUBLIC hospitals appear to have staved off threats of a public referendum on a takeover by the Federal Government.

Federal Health Minister Ms Nicola Roxon claimed public hospital performance had improved since the last election, following increased investment in emergency departments and $600 million in federal funding channelled into elective surgery.

Among its election commitments, Labor had promised to conduct a referendum to let voters decide if the government should take financial control of the nation's 750 public hospitals.

This would only happen if the states failed to adopt a major reform agenda and meet performance targets by mid-2009, following the injection of billions of dollars of additional funds.

The precise criteria on which the government will make a decision has not been made public, nor is it clear what would happen if some hospitals were found to be poor performers while others were operating successfully.

The Opposition accused the government of losing its nerve on the commitment.

"I don't think this government has an intention of taking [public hospitals] over," said Opposition health spokesman Mr Peter Dutton.

However, Ms Roxon said the government had insisted it preferred to work with states and territories to improve performance.

"I think people can see action and we remain committed to making an assessment about what will be a positive and constructive way to run our health system in the future," she said.

An official decision on a referendum is just one of the many difficult portfolio issues Ms Roxon has on her agenda. The government must still convince the Senate to pass its alcopops tax, first announced in the 2008 budget.

And it could face an uphill battle to get its plan to means test the 30% private health insurance rebate through Parliament too, after the opposition signalled it would vote against the measure.

Magnesium cuts cerebral palsy risk

MAGNESIUM sulphate can prevent cerebral palsy and gross motor disorders in the fetus when given to women at risk of very preterm births, a review shows.

Taking into account five trials, the reviewers found 63 women at risk of preterm births (up to 34 weeks gestation) needed to be treated with magnesium sulphate to prevent one case of cerebral palsy.

The authors wrote in *Obstetrics and Gynecology* (June), "... there is little doubt that antenatal magnesium sulphate therapy given to women at risk of preterm births is a neuroprotective agent against motor disorders for the preterm fetus".

"It reduced the rates of cerebral palsy and substantial gross motor dysfunction in early childhood," they wrote.

Professor Caroline Crowther, an obstetrician from the University of Adelaide who co-authored the Cochrane review, said the findings were exciting, even though they only applied to about 1% of births. "It is a very small, but important group," she said.

"Magnesium sulphate is a very inexpensive simple drug that can be used for preventing cerebral palsy. We don't really know how it works, but it is needed for all sorts of cells to function well."

Professor Crowther said the next step was to develop national guidelines about the use of magnesium sulphate.

The reviewers examined a large 2008 trial not considered in a previous Cochrane review, which found a significant reduction in the rate of cerebral palsy among the magnesium sulphate group compared with the placebo cohort at two years' follow-up.

In that study the magnesium sulphate was a 6g loading and 2g/hour maintenance infusion.

Sarah Colyer

Obstetrics and Gynecology 2009; 113:1327-33.