



30 July 2012

The General Manager
Adjudication Branch
Australian Competition and Consumer Commission
GPO Box 3131
CANBERRA ACT 2601

Via email: adjudication@acc.gov.au

17th Edition of Medicines Australia Limited Code of Conduct

Please find following CHOICE's comments on the above application from Medicines Australia Limited. This submission was authored by Dr Ken Harvey who represented consumers on the recent Government Working Group on Promotion of Therapeutic Products, is one of our Life Members and is a trusted expert on medical issues.

1. Disclosure

Medicines Australia now require member companies to submit aggregate amounts of all payments made to healthcare professionals for advisory boards and consultancy arrangements; attendance and speaking at medical conferences and educational events; and sponsorships for consumer organisations including the value of non-monetary support.

However, 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.^{1,2,3,4}

For example, the 2009 ACCC final determination noted,⁵

“At the pre-decision conference, the issue regarding the lack of transparency around the sponsorship of pharmaceutical companies to healthcare professionals to attend educational events, including international events, was raised. The ACCC encourages Medicines Australia

¹ <http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-review/submissions-to-20112012-code-review/>

² <http://medicinesaustralia.com.au/files/2010/01/Medicines-Australia-Report-final-16-April-2012-updated.pdf>

³ <http://theconversation.edu.au/code-for-pharmaceutical-industry-falls-short-8092>

⁴ <http://theconversation.edu.au/consumer-input-in-medicines-australias-code-of-conduct-review-6370>

⁵ <http://www.accc.gov.au/content/index.phtml/itemId/880195/fromItemId/401858/display/acccDecision>

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to continue to work with industry to increase transparency around the relationships between pharmaceutical companies and healthcare professionals”.

Since then, a number of Australian pharmaceutical companies have become comfortable with individual disclosure of payments to healthcare professionals⁶ along the lines of the U.S. Physicians Sunshine Act⁷ which, although delayed, will require reporting from January 1, 2013.

Medicines Australia has had 3 years to address this issue and have done nothing until the issue was raised again in the 2012 Code revision submissions. Their current plan is to set up a working group to give advice on this matter. That appears just more procrastination.

Medicines Australia CEO Brendan Shaw has said he is concerned that doctors known to have received pharmaceutical company payments will face tabloid media witch-hunts and also that the costs of collecting this information would be prohibitive. In response, we argue that health professionals receiving money for legitimate interactions with industry, such as the conduct of research, should have no concerns about this information being made public. In addition, given that member companies must currently collect this data internally to pay the doctors involved it is hard to see that forwarding this data to Medicines Australia would entail extra prohibitive costs.

We ask the ACCC to make full disclosure of individual payments to healthcare professionals an imposed “condition” for authorising the Code.

2. Sanctions

Medicines Australia maximum fine for a severe breach of their Code is \$300,000 (with an average fine of \$50,000). This stands in stark contrast to the recent GSK fine of \$3 billion by the U.S. Justice Department. Indeed, the GSK case is neither new nor alone. Settlements for criminal and civil monetary penalties from the U.S. pharmaceutical industry reached a total of \$20 billion in penalties during the 1991-2010 interval; \$15 billion of the settlements and penalties have occurred over the last 5 years. It is suggested that even substantial fines do little to change unethical behaviour; what is needed is jail terms for the company executives responsible.⁸

In Australia, we have seen some companies repeatedly breach Medicines Australia Code over the years which would seem to be prima facie evidence that the average \$50,000 fines is not an effective deterrent. Yet, despite this issue being raised in many submissions, the level of fines remained unchanged.

We ask the ACCC to substantially increase the maximum fine imposed as a “condition” for authorising the Code.

⁶ <http://www.theaustralian.com.au/news/health-science/glaxo-pushes-for-full-disclosure-on-funding/story-e6frg8y6-1226273120880>

⁷ <http://www.pewhealth.org/reports-analysis/issue-briefs/physician-payments-sunshine-provisions-in-health-care-reform-85899367974>

⁸ <http://www.bmj.com/content/341/bmj.c7360>

3. Monitoring Code effectiveness

The ACCC 2011 “Guidelines for developing effective voluntary industry codes of conduct”⁹ state that the Code administration committee, “should also produce annual reports on the operation of the code, allowing for periodic assessment of its effectiveness”.

While Medicines Australia does produce useful annual reports¹⁰ the data contained is in PDF format. In 2009, an article by Robinson, et al, “Mandatory Disclosure of Pharmaceutical Industry-Funded Events for Health Professionals” noted,

“We experienced considerable difficulty in accessing the Australian data, which are compiled in portable document format (pdf). As suggested in the US Sunshine Acts it is important that summary reports listing each function are accessible to the public in a searchable, downloadable, and analysable format”.¹¹

I have asked Medicines Australia to make their data on complaint outcomes and other material available in spread sheet format (Excel) rather than PDF format. This would facilitate an analysis of the number of upheld complaints per company over a 10 year period, the average fines imposed and whether or not Code compliance for a specific company was improving.

Unfortunately, I was advised that Medicines Australia did not have permission from member companies to disclose company data other than in the form published every six months on the Medicines Australia website (as prescribed by the ACCC).

We ask the ACCC to make publication of the data contained in Code reports to be accessible to the public in a searchable, downloadable, and analysable format.

4. Limitations of industry self-regulation

The procrastination on these issues illustrate a fundamental problems of self-regulation; codes often lag behind consumer and health professional views due to the absence of these stakeholders from code revision committees. Codes also lag behind the views of progressive pharmaceutical companies because of the need for revisions to be approved by a majority of member companies.

In addition, in Australia a plethora of therapeutic industry associations results in a variety of self-regulatory codes with code content, monitoring, complaint procedures and transparency varying greatly; it’s not a level playing field!

A further problem with self-regulatory codes is that they don’t apply to non-members; a major problem in certain areas of the Australian therapeutic goods industry. For example, earlier this year Ranbaxy Australia offered pharmacists A\$14,648 of free Trovas (generic atorvastatin) stock; an offer that would appear to breach the codes of both the Generic Medicines Industry Association (GMiA) and Medicines Australia. However, as Ranbaxy Australia Pty Ltd was not a member of any self-regulatory industry association no complaint could be heard!

⁹ <http://www.accc.gov.au/content/index.phtml/itemId/658186>

¹⁰ <http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-reports/>

¹¹ <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000128>

In 2011 a government “Working Group on Promotion of Therapeutic Products”¹² was set up to address these problems. Consumer and health professional representatives argued for one code, one efficient complaint (and monitoring) system and one set of effective sanctions applicable to all therapeutic claims and promotional activities regardless of the industry sector, media or target. This was to be administered by an independent Therapeutic Goods Promotion Agency comprised of all stakeholders. This concept was rejected by industry representatives.

The working group did recommend that each industry code should address common operation and governance areas in order to achieve greater consistency. In addition, to address the problem of non-members, they suggested that the government should make compliance with a code a condition of marketing approval. The latter was rejected by the government which first wants to evaluate the effectiveness of voluntary sign-up.

Ironically the ACCC 2011 “Guidelines for developing effective voluntary industry codes of conduct”⁵ notes that 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. Medicines Australia has yet to take this advice on-board.

We ask the ACCC to add consumer and health professional representatives to the Code governing body as a “condition” for authorising the Code.

5. Limitations of ACCC “authorisation” process

In 2006, the ACCC imposed “conditions” when authorising MA’s Code which strengthened its provisions;¹³ it is hoped the same may occur with respect to the recommendations above.

However, the ACCC’s role appears limited and it is possible that some or all of the above problems will only be solved by the government strengthening self-regulation, for example by requiring that self-regulatory bodies include external stakeholders at all levels of decision making, by mandating that compliance with a code is a condition of marketing approval and by providing remedies at law for refusal to comply with determinations and sanctions.¹⁴

If necessary, we ask the ACCC to liaise with the government in order to implement the above recommendations.

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¹² [http://www.health.gov.au/internet/main/publishing.nsf/Content/Consultation:
+Position+Paper+on+the+Promotion+of+Therapeutic+Goods](http://www.health.gov.au/internet/main/publishing.nsf/Content/Consultation:+Position+Paper+on+the+Promotion+of+Therapeutic+Goods)

¹³ <http://www.accc.gov.au/content/index.phtml/itemId/744908/fromItemId/729983>

¹⁴ http://www.dbcde.gov.au/digital_economy/independent_media_inquiry/ (Section 11.76)