



**Submission to**

**ACCC**

**on**

**17th Edition of**

**Medicines Australia Code**

**Submitted to ACCC - 30 July 2012**  
**By Loretta Marron, CEO FSM**



This submission is written by Friends of Science and Medicine (FSM).<sup>i</sup> Our organisation has more than 700 scientists, clinicians, lawyers and consumer advocates as supporters. We have no links to any industry. A key aim of our organisation is to ensure that Australians have access to therapeutic interventions based on sound clinical evidence; not promotional hype or commercial incentives offered to health care professionals. Medicines Australia Code is an example of self-regulation by a sector of the Therapeutic Goods industry. This raises our first concern; we believe self-regulation by industry is inevitably weak and self-serving.

For example, over the last 5 years, settlements by the U.S. Justice Department for criminal and civil monetary penalties from the U.S. pharmaceutical industry reached a total of \$15 billion.<sup>ii</sup> These settlements also included Corporate Integrity Agreement which stipulated major changes to the way companies do business and further penalties for non-compliance.<sup>iii</sup> In contrast Medicines Australia maximum fine for a severe breach of their Code is \$300,000 (with an average fine around \$50,000).

Medicines Australia says that Code compliance is increasing because the number of complaints has fallen over the last few years. However, unlike the U.S, Australia has no False Claims Act to encourage complainants (who get a 15%-30% reward of monies recovered by the government) and recent defamation actions against Australian complainants have had a chilling effect. In addition, although Medicines Australia has an independent monitory committee, we understand they have never monitored the behaviour of pharmaceutical representatives when detailing to health professionals despite this activity representing a substantial proportion of the promotional budget.

Furthermore, over a number of years, health professional and consumer submissions have argued for greater transparency in the relationship between pharmaceutical companies and health professional and consumer organisations, including details of the payments made to individuals and organisations and for what purpose. Individual disclosure of these payments continues to be resisted by Medicines Australia in the 17th Edition of their Code despite the fact that this is now mandated by the U.S. Physicians Sunshine Act.<sup>iv</sup>

We understand that some Australian pharmaceutical companies would be supportive of the ACCC imposing individual disclosure of payments involved in all new contracts between health professionals and pharmaceutical companies as a condition of Code authorisation. This would have the advantage that Medicines Australia (and/or individual companies) would not be blamed by health care professionals for the imposition of disclosure and it would create a level playing field.

The procrastination of Medicines Australia on these issues illustrates many of the problems of self-regulation; a plethora of therapeutic industry associations results in a variety of self-regulatory codes; it's not a level playing field. Codes 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

companies because of the need for revisions to be approved by a majority of member companies. Codes don't apply to non-members of industry associations, a major problem in certain sectors of the therapeutic goods industry.



Despite the problems outline above, the Australian Government’s preference is to maintain an emphasis on self-regulation!<sup>v</sup> Presumably this “preference” is because government does not pay the cost of the self-regulatory systems. However, the cost to industry is passed on to consumers regardless; in addition, the government (by subsidising pharmaceuticals, diagnostics and medical devises) pays the cost of inappropriate use driven by unethical promotion.

The ACCC 2011 'Guidelines for developing effective voluntary industry codes of conduct' 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.

Taking all the above into account we ask the ACCC to impose the following conditions when authorising the 17<sup>th</sup> Edition of Medicines Australia Code:

- 1. Transparent reporting of individual payments and gifts (and conversion to money amounts of 'in kind' payments and gifts like overseas travel expenses to international meetings) made to health care professionals in the same way the USA Sunshine Act requires.**
- 2. Add consumer and health professional representatives to the Code governing (and Code revision) body.**
- 3. Conduct and report random monitoring of drug representative compliance with the Code when detailing to health professionals.**
- 4. Substantially increased levels of fines for Code breaches.**
- 5. Provide cumulative 10-year reports that allow upheld complaints to be tracked by company, code breach, sanction and level of fines over the years.**

## References

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<sup>i</sup> <http://www.scienceinmedicine.org.au/>

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

<sup>iii</sup> [http://oig.hhs.gov/fraud/cia/agreements/GlaxoSmithKline\\_LL\\_C\\_06282012.pdf](http://oig.hhs.gov/fraud/cia/agreements/GlaxoSmithKline_LL_C_06282012.pdf)

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

<sup>v</sup> <http://www.health.gov.au/internet/main/publishing.nsf/Content/Consultation%3A+Position+Paper+on+the+Promotion+of+Therapeutic+Goods>