

**Submission to the Australian Competition and Consumer Commission (the ACCC) regarding Medicines Australia Limited (MA) application for revocation of authorisations A91316- A91320 and substitution of new authorisations A91436-A91440**

This submission focuses on the ACCC requirements as follows:

1. the likely public benefits and effect on competition, or any other public detriment, from MA's proposed arrangements.
2. information with regard to the general experience of the arrangements during the term of the previous authorisation.
3. views on the public benefits and detriments we consider have actually resulted from the arrangements during the previous authorisation period.

The likely public benefits and effect on competition from MA's proposed arrangements do not fully address the role of an industry body attempting to maintain standards of disclosure as outlined by the [Transparency Reporting Model Consultation Discussion Paper](#). This point has been raised previously in the 16th Edition (2009) Code revision and again in the 17th Edition (2012) Code revision.

For example, the [2009 ACCC final determination](#) noted, "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 to continue to work with industry to increase transparency around the relationships between pharmaceutical companies and healthcare professionals". In 2014 this issue continues to be unacceptable and very difficult to measure.

Finding evidence for any public benefits and detriments that may have arisen from the arrangements during previous authorisation period requires hours of trawling through Medicines Australia web site searching quarterly reports.

From 2009 to 2013 the total number of breaches of Medicines Australia's Code of Conduct has declined from 15 in 2009 to 7 in 2013. The overall amount of fines collected by Medicines Australia over the last 6 years was \$3,027,000.

31% or 29 pharmaceutical companies had 94 complaints between them with 52% or 49 of them paying fines (that is 45 were found to not have breached the MA code of conduct).

Most or 35% (33) complaints were submitted by the pharmaceutical industry: 29% (28) by health care professionals, 24% (22) by Medicines Australia Monitoring Committee, 7% (7) by members of the general public and 4% (4) various.

29 pharmaceutical companies paid fines totally \$3,027,000. The fines ranged from \$1,000 to \$445,000.

Types of breaches ranged from 64% or 60 using misleading promotional materials to 13% or 12 educational events representative conduct, 7% or 7 media releases and 12% making up misleading presentations, starter packs, news items and advertisements in advertorials.

The 2011 ACCC *Guidelines for developing effective voluntary industry codes of conduct* state that the Code Administration Committee, "should also produce annual reports on the operation of the code, allowing for periodic assessment of its effectiveness".

These reports do not inform the general public whether the Medicines Australia Code of Conduct (since 2009) have made a difference. In fact the reports raise a number of important questions.

In 2012 when monitoring the Medicines Australia Code of Conduct the [ACCC \(proposing to authorise pharmaceutical industry Code of Conduct for three years\)](#) said that outstanding issues associated with a framework for individual disclosure should be substantially addressed in the next 12 to 18 months, before an amended Code be implemented. Furthermore, ACCC Commissioner [Sarah Court](#) said: "Improving transparency around payments to individual doctors will play an important role in promoting community confidence in the integrity of these payments to healthcare professionals".

There is strong public support for greater transparency particularly in relation to the potentially harmful results of marketing by the pharmaceutical industry. The 2012-13 federal budget included \$1.14 million over four years to strengthen codes of conduct and transparency in industry promotion of therapeutic goods. In Senate Estimates May 2012 Senator Di Natale questioned the Therapeutic Goods Administration (TGA) on a range of issues [Community Affairs Legislation Committee - 31/05/2012 - Estimates - HEALTH AND AGEING PORTFOLIO - Therapeutic Goods Administration](#). Senator Di Natale asked for information from the TGA working group regarding the funding and advice on any outcomes for the current model of self-regulation. [The TGA](#) reported that further work would occur in 2013-14 to finalise principles for publishing committee meeting information. Information appears to have ceased from December 2013.

There was also support from the pharmaceutical industry to increase transparency with GSK making the statement that "[GSK is the first pharmaceutical company in Australia to make public the aggregate amount it spends with healthcare professionals and related organisations](#)". GSK has been disclosing individual payments to patient and community groups for the last four years. The total amount provided to health care professionals was over \$6.5 million. [Each year GSK provided healthcare professionals](#) with funds that ostensibly breached the MA Code of Conduct. These breaches are not reflected in MA Quarterly reports.

There was also support for more transparency from the Australian Medical Association (AMA) as reported by Julia Medew <http://www.smh.com.au/national/move-to-reveal-doctor-drug-deals-20130429-2ip17.html#ixzz2RzS85XLZ>. Dr Hambleton, the former President of the AMA said reports of overseas doctors receiving hundreds of thousands of dollars from companies in the US had made the AMA fear that continued secrecy could undermine confidence in the integrity of doctors here. "We're on the pathway to transparency, it's really a matter of working out an appropriate mechanism," he said.

Medicines Australia Code does not adequately reflect current demands being expressed by the industry, the medical profession and the public for greater transparency.

Medicines Australia argues that disclosing transfers of value from those health professionals who consent to disclosure of payments (and adding together the total value of benefits received by those health professionals and the numbers of those who do not consent) is an incremental improvement (and public benefit) on the previous Code and thus their latest Code should be authorised by the ACCC.

The alternative view is that it would be to the public detriment to authorise a Code that fails to deliver on the key principles agreed to by the Medicines Australia Transparency Working Group, including the key outcome raised by many interested parties in deliberations about edition 17 of the Code: the transparency of individual payments made to healthcare professionals (consistent with developments in the U.S.).

Accordingly, I agree with the view that the ACCC should not authorise edition 18 of the Medicines Australia Code as it fails once again to provide any public benefits with regards to transparency. Rather they should defer authorisation and refer the Code of Conduct back to where the responsibility lies: the Regulatory Policy & Governance Division of the Australian Department of Health, the Therapeutic Goods Administration (TGA) and the government, all of whom have failed to address the limitations of self-regulation. What is needed is Australian legislation that makes transparency (and other ethical considerations) a condition of market authorisation by the TGA.