



The Royal  
Australian &  
New Zealand  
College of  
Psychiatrists

30 July 2014

Dr Richard Chadwick  
General Manager  
Adjudication Branch  
Australian Competition and Consumer Commission  
23 Marcus Clarke Street  
CANBERRA ACT 2601

By email to: [adjudication@accc.gov.au](mailto:adjudication@accc.gov.au)

Dear Dr Chadwick

**Re: A91436-A91440 – Medicines Australia Limited – submission.**

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) welcomes the opportunity to provide feedback to the Australian Competition and Consumer Commission's (ACCC) consultation about Medicines Australia's proposed *Code of Conduct, Edition 18* (Code of Conduct).

The RANZCP wishes to comment on Section 41 of the Code of Conduct. Section 41 introduces an enhanced transparency regime for reporting transfers of value between pharmaceutical companies and Australian healthcare professionals. The regime comes into effect from 1 October 2015.

The RANZCP welcomes the enhanced transparency provisions in Section 41 of the Code of Conduct and supports efforts by Medicines Australia to introduce greater transparency for transfers of value between pharmaceutical companies and healthcare professionals.

However, to maximise the public benefit value of the transparency provisions, the RANZCP considers that there are two key improvements that can be made to the Code of Conduct. These are in the areas of clinical research and transparency reporting.

The RANZCP previously made a submission to Medicines Australia on these issues in September 2013 in response to Medicines Australia's *Code of Conduct Review of Transparency Model Consultation and Discussion Paper*. This submission can be found on our [website](#).

### **Clinical research**

Section 41.3.1 of the Code of Conduct lists items that pharmaceutical companies must report as transfers of value to healthcare professionals from 1 October 2015.

One category of reportable transfers of value is fees paid by pharmaceutical companies to healthcare professional consultants (or to their employers on their behalf) for specific services such as the preparation of promotional material or training assistance. However, this category does not include "payments to consultants in relation to research and development work, including the conduct of clinical trials."

The RANZCP considers that there is a need to more explicitly address the relationship between healthcare professionals and the pharmaceutical industry in the funding of clinical research and the use of 'key opinion leaders' in promoting the outcome of that research.

Healthcare professionals may act as key opinion leaders through their work on advisory boards and consultancy work with pharmaceutical companies. The RANZCP notes that Section 41.3.1 identifies these activities as transfers of value that must be reported by pharmaceutical companies. Healthcare professionals may also act as key opinion leaders by being involved in clinical research and development work funded or sponsored by pharmaceutical companies. Yet, while the conduct of clinical trials is one of the most costly elements of research work, the Code of Conduct specifically excludes it from the categories of transfers of value that pharmaceutical companies must report.

Therefore, to enhance the Code of Conduct's transparency regime, the RANZCP believes that it is essential for fees paid for research and development, including clinical trials to be included as a reportable item in Section 41.3.1. Doing so will improve the public benefit value of the Code of Conduct because it would enable health professionals to more effectively evaluate research by taking into account their funding sources while also providing greater visibility for a wider range of transfers of value.

### **Transparency Reports**

Section 41.3 of the Code of Conduct indicates that each pharmaceutical company must publish transparency reports of transfers of value to healthcare professionals. Each transparency report must list details of individual health practitioners who receive transfers of values, including their name, principal practice address and a date and description of the relevant service or event.

Under the Code of Conduct, pharmaceutical companies must obtain informed consent from healthcare professionals to publish transfer of value information relevant to them. They must also give healthcare professionals the opportunity to review and submit corrections to their information. If a healthcare professional does not agree to this information being disclosed with their name, the pharmaceutical company must report the expenditure in aggregate with the number of healthcare professionals it relates to.

However, to maximise the public benefit of the Code of Conduct, the RANZCP considers it appropriate that healthcare professionals consent to have their name included in the transparency report. This is consistent with RANZCP's [ethical guidelines](#), which emphasise the importance of openness and transparency in dealings between individual psychiatrists and pharmaceutical companies, including disclosure of financial or any other arrangements.

Under Section 41.3, a pharmaceutical company must publish transparency reports every six months and this information must remain available for two years on the company's website. The most senior executive officer of the company must also provide Medicines Australia with a declaration that it has published the required report on the relevant company's website.

This proposed approach means that a person must look at each individual pharmaceutical company website in order to access information about transfers of value to healthcare professionals rather than go to one central source of information. As healthcare professionals may receive transfers of value from more than one pharmaceutical company, the RANZCP considers that Section 41.3 makes it difficult for any interested person to aggregate or analyse data about transfers of value to healthcare professionals.

Therefore, to enhance the public benefit of the transparency regime, the RANZCP believes that these transparency reports should be made to an independent body. This body should have the capacity to provide analysis, present information in a meaningful way and publish that information in the public domain. The RANZCP recommends that this could be an existing organisation that has both the capacity and the track record to undertake such work, such as the Australian Institute of Health and Welfare.

### **Engagement with the pharmaceutical industry**

The RANZCP has recently developed a [Position Statement](#) regarding engagement with the pharmaceutical industry. While the Position Statement specifically refers to the engagement between the RANZCP as a professional organisation and the pharmaceutical industry and not the relationship of individual members or research institutions with the industry, it may be a useful resource for the ACCC.

If you would like to discuss any of the issues raised in the submission, please contact Dr Anne Ellison, General Manager, Practice, Policy and Projects, via [REDACTED] or by phone on [REDACTED]

Yours sincerely



**Dr Murray Patton**  
**President**

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