

16 September 2013

Code of Conduct Manager
Medicines Australia.

Dear Sir/Madam,

Thank you for the opportunity to provide input to the Medicines Australia Transparency Model – Consultation and Discussion Paper. I write specifically in relation to sections 3.8 and 5.9.

Throughout this document and in all correspondence I make my comments as a private individual and not in my capacity as an employee of Monash University and Eastern Health, or as director of ANZUP Cancer Trials Group or of the Clinical Oncology Society of Australia.

Personal background:

I am a medical oncologist and Professor of Medicine and Head of the Eastern Health Clinical School, Monash University and Eastern Health, in Melbourne, Australia. I am founder of the Urologic Oncology Group of the Clinical Oncology Society of Australia (COSA), a member of COSA Board and COSA Council; and am founder of the Australian and New Zealand Urogenital and Prostate Cancer Trials Group Ltd (ANZUP). I am member and/or chair of multiple industry advisory boards as listed below. I receive no remuneration for any of this activity. All payments and honoraria are invoiced by and paid to ANZUP Cancer Trials Group.

Industry advisory board involvement (unremunerated):

- 2005- Member, Pfizer Renal Cell Carcinoma Advisory Board (Chair from 2009)
- 2008- Member, Novartis RAD001 Advisory Board
- 2009- Chair, GlaxoSmithKline Pazopanib (Renal Cell Carcinoma) Advisory Board
- 2010- Chair, Janssen Abiraterone Advisory Board
- 2010- Member, Medivation MDV3100 international advisory board
- 2011- Member, BMS ipilimumab advisory board
- 2012- Member, Sanofi Jevtana advisory board
- 2012- Member, BMS anti-PD1 advisory board
- 2012- Chair, Bayer Asia-Pacific Radium-223 dichloride advisory board
- 2013- Member, Astellas Oncology Portfolio Advisory board

Company Boards (unremunerated):

- 2008- Director and Chair of the Board, Australian and New Zealand Urogenital and Prostate Cancer Trials Group Limited (“ANZUP”)
- 2013- Director / Board member, Clinical Oncology Society of Australia (COSA)

Background with respect to sections 3.8 and 5.9:

- I am a clinician-researcher
- It is imperative for clinician-researchers to interact with industry in order to be able to secure industry-sponsored clinical trials for Australian patients and researchers

- Relationships with industry also help to facilitate opportunities for investigator-initiated research including cooperative group trials
- I recognise the ethical complexities and have made a personal decision to accept no payment for any work I perform with industry
- Honoraria or other payments are therefore invoiced by and paid directly to ANZUP Cancer Trials Group (www.anzup.org.au), which is a not-for-profit cooperative cancer clinical trials group, a company limited by guarantee. I am an unremunerated director and chair of ANZUP. ANZUP is a registered charity in all Australian states and territories with tax deductible gift recipient status. The purpose of ANZUP is to perform clinical trials in patients with genitourinary cancers. These honoraria are a very useful supplement to ANZUP's revenue and assist it to operate, as its funding through the Federal Government does not come close to covering its costs. I certainly receive no benefit personally from directing payments to ANZUP.
- As a result of this arrangement, no industry money passes through my hands. This satisfies the "front page of the newspaper" test for me and, although it does not address all of the ethical questions regarding relationships with industry, I am very happy with this process. I have always held this as the basis under which I will continue to work in these ways with industry.
- I have recently been informed by several companies that this arrangement cannot continue due to advice from "compliance." On further investigation it appears that the concerns related to the US Foreign Corrupt Practices Act or to possible avoidance of income tax. However:
 - The US Foreign Corrupt Practices Act is not relevant to this arrangement.
 - There is no avoidance of income tax: if I receive the payment and then donate it then I must declare it as taxable income; however, as ANZUP is a charity I am able to deduct 100% of the donation. Therefore I would not be paying income tax on it anyway.
 - Additionally, GST is payable under my arrangement for Australian work and so the federal government is now actually getting something from the process, rather than missing out entirely.
- I sought advice on these issues from Medicines Australia but unfortunately this was unhelpful.
- I have also discussed the situation with Mr Glenn Ferguson, lawyer and a director of ANZUP, who advised me that my arrangement was acceptable. Mr Ferguson advised that I set up a formal arrangement with ANZUP to direct all these payments to ANZUP (see attached).

Some companies continue to have concerns over these arrangements and I have informed them that I will not operate with them under any arrangement that essentially forces me to accept money from them. However, neither am I prepared to donate my time and expertise to these companies to reap the benefits entirely free of charge to them. Again, the arrangement with ANZUP satisfies these needs.

It seems that these companies' compliance departments are determined to push money into my pocket. These processes directly encourage and almost enforce exactly the sort of behaviour that should not be encouraged and that they should not want. I believe that my behaviour has been of a

high ethical standard and, although I do not require it of others, perhaps others could consider it as a model for their interactions with industry.

It is my strong opinion that Medicines Australia should actively work to prevent companies from imposing these sorts of requirements and that this should be reflected in the Code of Conduct.

Specific comments:

- Section 3.8: Payments to third parties, including registered charities

3.8.1 If the payment or other transfer of value was provided to a third party organisation, including a registered charity, at the request of or designated on behalf of a healthcare professional, the payment or transfer of value must be reported in the name of that healthcare professional. The name of the organisation that received the payment or other transfer of value must also be stated in the report.

It seems pointless for all payments to be made independently of the healthcare professional but then to be reported in the name of that professional. It would be more logical to report payments in the name of the charity (the recipient and beneficiary of the payment) and to document for transparency the name of the healthcare professional whose activities led to the payment; but not to link the payment to that individual.

3.8.2 If the payment or other transfer of value was provided to another person at the request of or designated on behalf of a healthcare professional, the payment or transfer of value must be reported in the name of the healthcare professional. The name of the person who received the payment or other transfer of value need not be disclosed, but stated as “payment to another individual”.

This process also lacks transparency in exactly the same way as a process of nondisclosure of the name of a healthcare professional receiving payment. The other individual should be named.

3.8.3 If a healthcare professional performed a service, but neither accepted the offered payment or other transfer of value nor requested that it be made to a third party, the company is not required to report the offered payment or other transfer of value, even if the company made an equivalent payment or donation to a third party organisation or a registered charity of its own choice.

Such payments should still be reportable in the interests of transparency.

Boxed text 3.8. Payments to third parties, including registered charities:

- “Is the balance right? Does Section 3.8 sufficiently explain where the balance should lie between appropriate transparency and avoiding inappropriate attribution of a payment?”

The balance is not right, as described above.

3.8.1 incorrectly places the healthcare professional at the centre of a transaction not involving them.

3.8.2 and 3.8.3 are insufficiently transparent.

- Section 5.9 (to be considered with section 3.8)

This section is to be considered as an exclusion from reporting. I have commented on this in relation to 3.8.3 above.