

**RANZCO**The Royal Australian
and New Zealand
College of Ophthalmologists

THE MEDICAL EYE SPECIALISTS

20 September 2013

Secretary Code of Conduct Committee
Medicines Australia
16 Napier Close
DEAKIN ACT 2600

By email: secretarycodecommittee@medicinesaustralia.com.au

Dear Mr Fladrich

Submission in response to the Review of the Medicines Australia Code of Conduct

The Royal Australian and New Zealand College of Ophthalmologists (RANZCO) thanks Medicines Australia (MA) for the opportunity to comment on its *Transparency Model Consultation and Discussion Paper*.

RANZCO's mission is to drive improvements in eye health care in Australia, New Zealand and the Asia Pacific Region through continuing exceptional training, education, research and advocacy. Underpinning all of the College's work is a commitment to best patient outcomes, providing contemporary education, training and continuing professional development, evidence-based decision making, collaboration and collegiality. RANZCO also seeks to educate the general public in all matters relating to vision and the health of the human eye and advocates for accessible ophthalmology services for patients.

RANZCO supports efforts to ensure any relationship between ophthalmologists and industry is transparent and publicly acknowledged. RANZCO's position on this important issue stems from the College's policy on *Ophthalmologists and Trainees Interactions with the Medical Industry* which is appended to RANZCO's *Professional Code of Conduct* and largely aligns with provisions in the Australian Medical Council's *Good Medical Practice: A Code of Conduct for Doctors in Australia*.

All Fellows and trainees of the College are expected to adhere to the principles and practices outlined in RANZCO's *Professional Code of Conduct*.

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Specific comments in response to the questions raised in the Consultation and Discussion Paper are set out below.

Page 2 - Glossary

The terms and explanations included in the Glossary are sufficient and clear.

Page 3 - General Requirement & Limitations: Scope of the transparency model

RANZCO supports a transparency model that leaves the possibility for all therapeutic goods companies to be covered, not just the voluntary pharmaceutical company members of MA.

As ophthalmology is both a surgical and medical specialty, RANZCO Fellows interact with both medical device and pharmaceutical companies. As can be observed from the Medical Technology Association of Australia's *Medical Technology Industry Code of Practice*, the ethical obligations owed are similar irrespective of the type of therapeutic good. Activities such as cross-subsidisation of equipment and 'bundling' (where companies discount one item in order to drive use of another more expensive item) are commonplace in the medical technology industry. The transparency model should enable such activities to be subject to similar scrutiny. This would provide clarity and consistency for ophthalmologists with regard to their ethical obligations.

With respect to reporting, RANZCO oppose the Australian Health Practitioner Regulation Agency (AHPRA) being the organisation responsible for managing transparency reports. Having this responsibility fall within the remit of the healthcare professionals' registration body could significantly perpetuate the perception that interactions between practitioners and pharmaceutical companies are not legitimate. In truth, it is widely accepted that such interactions can be beneficial for patients.

The creation of a separate Foundation to manage reports, as has occurred in The Netherlands, would recognise that the ethical responsibility for practitioner-industry interactions does not solely fall on practitioners, and would assist in dispelling sensationalised accounts of practitioners being given gifts and hospitality. However, this solution risks increased red tape, costs to tax payers, and costs transferred to patients.

RANZCO therefore supports the management of reports by MA, and the Government taking steps toward requiring all non-MA member therapeutic companies to nominate reporting rules to which they will adhere. While this may lead to multiple repositories for reports, an existing Government

body such as the Therapeutic Goods Administration can play a role in educating practitioners and creating efficiencies when a practitioner has to verify, correct and/or dispute a report.

Page 4 - Identifiers for healthcare professionals

RANZCO does not oppose use of the AHPRA registration number for uniquely identifying healthcare professionals for the purpose of the transparency model.

Page 5 - Category of payment or transfer of value

RANZCO agrees the listed categories suitably cover and define the different types of payments and transfers of value that a company may offer to a practitioner.

Page 7 - Payments to third parties, including registered charities

Section 3.8 achieves the correct balance between appropriate transparency and avoiding inappropriate attribution of a payment. It is worth pointing out that for this to work in practice and to ensure accurate reporting, MA's *Code of Conduct* must not only direct companies to keep an ongoing record of when a practitioner accepts a payment/transfer of value or requests that it be made to a third party; but must also direct companies to record when a practitioner neither accepts the payment/transfer of value nor requests that it be made to a third party.

It is agreed that payments made to third parties by the company of its own volition should not be attributed to any healthcare professional.

Page 7 - Requirements for payments or other transfers of value related to continuing professional development programs

RANZCO agrees it is reasonable for companies to be exempt from reporting payments/transfers made for a healthcare professional to speak at a CPD program where the CPD program meets AHPRA's CPD registration standards, where the company does not pay the healthcare professional directly and where the company has little influence on the identity of the healthcare professional. The College considers that payments/transfers of value to healthcare professionals for attending and not speaking at a CPD program should be subject to reporting requirements in all circumstances. References to the word 'attending' and 'attendee' at paragraph 4.1 of the Consultation and Discussion Paper should therefore be removed from the exemption.

Other relevant standards for CPD that the transparency model could reference are the CPD standards set by the individual medical colleges (which are often set higher than the AHPRA

standard), as well as the standards adhered to by the medical colleges who undertake CPD accreditation of educational events.

Page 9-10 - Reporting threshold and non-hospitality and non-travel costs

RANZCO has no specific opinion on the reporting threshold. This is a matter for pharmaceutical companies and their internal financial controls and capabilities.

The College does not support function costs (non-hospitality and non-travel costs such as audio-visual and room hire costs etc.) being included in the information about payments and transfers of value in a manner that would attribute and distribute these costs amongst the delegates or attendees at a meeting. This is because an individual ophthalmologist delegate/attendee cannot exert any influence or control over such costs. Moreover, it cannot be assumed that each practitioner will receive an equal share in the 'value' of the function. While RANZCO believe function costs should be subject to public scrutiny it is disingenuous for these costs to be ascribed to individual practitioners.

Page 10 - Clinical research

Section 5.3 adequately describes and defines clinical research activities.

Page 11 - Starter packs

RANZCO agrees that starter packs should be excluded from the transparency reporting requirements because the healthcare professional is not personally receiving a transfer of value. The broader ethics regarding the use of starter packs/product samples should be addressed in the body of MA's *Code of Conduct*, and not by whether their value is reported or not.

Page 12 - Payments for Expert witness in legal or administrative proceedings

RANZCO agrees that payments to healthcare professionals acting as an expert witness in legal or administrative proceedings should not be required to be reported. As alluded to in the Consultation and Discussion Paper, expert witnesses are subject to a number of codes of conduct which expressly state that the expert's duty is to the court and not to any party which is commissioning the evidence or paying for the testimony. Expert witnesses are not entitled to offer opinions and courts are entirely able to reject witnesses and evidence. There are added sensitivities around litigation-related costs that must also be respected and that make them inappropriate for inclusion in reporting requirements.

Page 12 - Procedures for electronic submission of reports

Specific comments regarding the management of reports are set out above on pages 2 and 3.

Page 13 - Notification

RANZCO commend MA on the inclusion of the mechanism to allow health professionals 45 days to review and verify payments and transfers of value attributed to them.

Page 14 - Data disputes

It is agreed that a procedure for data disputes must be included in the transparency model, especially given the heavy reliance on good record keeping by companies and practitioners.

Having said that, RANZCO believe 1 year is too long for disputed data to be published without revision. It is recommended that an interim version (updated to reflect corrected data) should be published 6 months later on 31 November of each year. As an alternative, data sets could be colour coded to highlight which data has been verified by both parties and can therefore fairly be scrutinised. In all circumstances a disclaimer should point out the potential for inaccuracy in reporting.

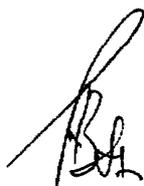
Page 15 - Updating the information

RANZCO agree there should be a period after which historical information is removed from the website, such as 5 years.

As a final comment, it is critical that reporting is completed accurately and fairly given the potential effects public scrutiny of payments can have on a healthcare practitioner's reputation.

Should you require any further information in relation to this submission please contact Ms Ritu Mohan, RANZCO Policy Officer, at rmohan@ranzco.edu.

Yours sincerely



Dr Stephen Best
RANZCO President