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Secretary
Code of Conduct Committee
Medicines Australia
16 Napier Close
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Email: secretarycodecommittee@medicinesaustralia.com.au

Dear Sir / Madam

Review Medicines Australia Code of Conduct

Thank you for the invitation to provide feedback to the Medicines Australia Code of Conduct "Review of Transparency Model Consultation and Discussion Paper" by The Cardiac Society of Australia and New Zealand.

The Review was co-ordinated through the Society's Professional and Ethical Standards Committee (PESC) chaired by Associate Professor John Atherton.

PESC have considered the Consultation Discussion Paper and our Committee members provide the following comments:

2. Limitations
What is your preferred option for management of the transparency reports?

Agree that all therapeutic goods companies should be included in this program. Thus the agency receiving the report needs be broader than Medicines Australia.

3.3 Identifiers for healthcare professionals
What are the practical requirements for pharmaceutical companies and healthcare professionals with respect to a unique identifier, in order to implement a transparency model?

The AHPRA registration number is an obvious way to uniquely identify a health professional. The real question is do health professionals have the right to protect their involvement with pharmaceutical companies? Some of these interactions could be commercially sensitive. There would need to be a very robust mechanism to ensure the information was secure and even then a health professional could make a strong argument that involvement with a company is their private business and should not be disclosed to any 3rd party. This of course does not reduce the importance of declaring that involvement when publishing research or discussing products in a public forum or scientific meeting.

3.7 Category of payment or transfer of value
Do these categories sufficiently cover the types of payments and transfers of value that occur? Are there other categories that should be added, or can some categories be deleted?

Are the categories well enough defined to enable companies to categorise payments or other transfers of value?

The list seems to be reasonably comprehensive. It does not include current or prospective ownership or investment interest held by a family member of the healthcare professional. However, whilst this could be perceived as a potential conflict of interest, it may be problematic to record this information that would presumably require the consent of the family member (if their identity could be indirectly determined). Furthermore, it would be unlikely that the company would have access to this information and it would be almost impossible to manage this process.

3.7 c) Honorarium – Most of what is generally understood by this term is covered in the other parts of 3.7. If there is need for a miscellaneous payment the nature of the service should be specified.

3.8 Payments to third parties, including registered charities

...On the other hand, if a healthcare professional declines to receive a payment and does not request that the payment be made to another person or organisation instead, but such a payment is made by the company of its own volition, there is an argument that the payment should not be attributed to the healthcare professional.

Agree with last sentence.

Section 3.8 suggests a way to achieve a balance between these options.

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?

This seems to be a reasonable compromise.

4. Requirements for payments or other transfers of value related to continuing professional development programs.

It is reasonable to exclude transparent reporting of payments to health professionals associated with formal, independent CPD. However, there is still the potential to influence medication use/equipment choice when funds are made available to CPD programs even when individual speakers/attendees are not chosen. Hospitals run CPD programs and the availability of funds for that program could influence subsequent negotiations especially when bulk supplies are being considered. Thus would suggest that these payments should not be excluded from the transparency reporting requirements, however these payments would be attributed to the organisation arranging the CPD program.

5. Exclusions from reporting

Reporting threshold

...The transparency model for consultation therefore includes both options for consultation.

Suggest that the $25 threshold is more practical and likely to have adequate impact on any influence this payment might have on the health professional. The $10 level would simply create huge bureaucracy with minimal gain.

What are the practical implications of different thresholds for recording and reporting of payments and transfers of value, for both companies and healthcare professionals?

Should function costs (non-hospitality and non-travel costs) be distributed amongst the delegates or attendees at a meeting, and therefore included in the information about payments and transfers of value?

Do you agree that changing the threshold each year in line with the CPI is appropriate? Is there an alternative approach that you would recommend?

This comes back to the comment re unrestricted grants for CPD. Suggest that a total sum should be declared and perhaps broken down into broad categories of hospitality, travel and logistics. It would have been thought that these costs would all be related to approved CPD programs and as such could go to the body organising the meeting rather than individuals.

Industry play a vital role in facilitating educational meetings and we need to recognise and acknowledge that. Certainly there is a benefit to them however if we get the balance wrong with this program everyone will lose out. The purpose of this program it seems is to create transparency rather than barriers to this interaction. Thus keeping the reporting requirements as simple as possible is important.

Increasing thresholds with CPI seems reasonable.

5.3 Clinical research

Does Section 5.3 adequately describe and define clinical research activities?

Yes. Does not need to be overly specific however perhaps requiring the research to be approved by an external body such as an ethics committee may be worth considering.

5.4 Starter packs

Do you agree that starter packs should be excluded from the transparency reporting requirements?

Yes

5.11 Payments for Expert witness in legal or administrative proceedings

What is your view on whether payments to healthcare professionals when they are acting as an expert witness should be included in or excluded from reporting requirements?

All payments should be reported to maintain complete transparency.

If the healthcare professional is appearing in legal or administrative proceedings, the professional's independence could be questioned if they are receiving payments from a company. These payments should not be excluded.

6. Procedures for electronic submission of reports

No strong feeling regarding the 1st issue over and above what was said earlier. Not sure that there would be many health professionals who would spend much time reviewing any of this information so probably academic.

7.4 Data disputes

Is this procedure fair and appropriate?

Can you suggest an alternative procedure that would ensure that accurate data is published, but the publication of information is not unreasonably delayed whilst a dispute is resolved?

The publication of data that is disputed seems inherently unfair. The fact that there is dispute could be published however the details should be correct before being released.

Thank you again for the opportunity to participate in the Review.

Yours sincerely

John Atherton
Chair
Professional and Ethical Standards Committee