The Royal Australian & New Zealand College of Psychiatrists
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17 September 2013

Ms Sophie Hibburd
Secretary Code of Conduct
Medicines Australia
Level 1, 16 Napier Close
DEAKIN ACT 2600

By email to: secretarycodecommittee@medicinesaustralia.com.au

Dear Ms Hibburd

Re: Medicines Australia's Code of Conduct Review of Transparency Model Consultation and Discussion Paper

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) welcomes the opportunity to provide feedback into Medicines Australia's Code of Conduct *Review of Transparency Model Consultation and Discussion Paper.*

The RANZCP supports initiatives to increase transparency regarding payments and transfers of value between companies and healthcare professionals. We have concerns that the Transparency Model does not sufficiently address issues relating to clinical research activity and recommend further development of this aspect of the Model. Question 8 addresses our specific concerns with suggestions that we believe will enhance the Model.

The RANZCP recently developed a Position Statement regarding engagement with the pharmaceutical industry. While this statement refers specifically to the engagement between the RANZCP as a professional organisation and the pharmaceutical industry, and not the relationship of individual members, research institutions, or other relevant parties with the industry, it may be a useful reference for Medicines Australia. The Position Statement is at: https://www.ranzcp.org/Files/ranzcp-attachments/Resources/College_Statements/PS-78-PPP-Pharma-engagement-policy-intentions-of-p.aspx.

If you would like to discuss any of the issues raised in the submission, please contact Dr Anne Ellison, via anne.ellison@ranzcp.org or by phone on (03) 9601 4918.

Yours sincerely

Dr Murray Patton
President

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The Royal Australian & New Zealand College of Psychiatrists

Submission to Medicines Australia Code of Conduct Review
Transparency Model Consultation and Discussion Paper

13 September 2013

Introduction

The Royal Australian and New Zealand College of Psychiatrists (RANZPC) welcomes efforts by Medicines Australia to increase transparency about payments and transfers of value between companies and health professionals.

Discussion Paper questions

1. Glossary

1.1. Are there other terms used in the model which should be included in the Glossary with an explanation?

No.

2. General Requirements and Limitations: Scope of the transparency model

2.1. What are the advantages and disadvantages of these different options for who should receive and publish the reports? Are there other options that should be considered?

The RANZCP would caution against using the Australian Health Practitioners Registration Agency (AHPRA) for this purpose, due to the risks of conflating issues with Medicines Australia and the registration of medical practitioners.

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

An annual report to an independent body is preferred. The latter should have the capability and capacity to provide analysis, present the information in a meaningful way and in the public domain The RANZCP recommends 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 (AIHW).

3. Identifiers for healthcare professionals

3.1. Are there other options for uniquely identifying healthcare professionals for the purpose of the transparency model? What are they and what are their advantages?

An additional identifier is not necessary – a practitioner's existing AHPRA number is sufficient.

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

See the response to 3.1 – an additional number is not necessary.

4. Category of payment or transfer of value

4.1. 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?

The RANZCP has no response to this question.

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

They are comprehensive and well-defined. No further categories are required.

5. Payments to third parties, including registered charities

5.1. Section 3.8 suggests a way to achieve a balance between these options. Is the balance right?

Yes.

5.2. Does Section 3.8 sufficiently explain where the balance should lie between appropriate transparency and avoiding inappropriate attribution of a payment?

Yes, the balance between transparency and avoiding inappropriate attribution of a payment is balanced. However, the RANZCP would like further clarification on whether a declaration of connections or interests outside of a health care role between professionals and the charity nominated is required. .

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

6.1. Is it reasonable to exclude payments or transfers of value associated with formal, independent CPD from the transparency reporting requirements?

It is reasonable to exclude payments from transparency reporting requirements if the criteria listed have been met.

6.2. Are the circumstances in which a payment or transfer of value to a healthcare professional in association with a CPD activity would not be required to be reported sufficiently well described and defined?

The RANZCP has no comment.

6.3. Are there other relevant standards for CPD that the transparency model could reference in relation to Section 4?

Payments to health care professionals for CPD activities, regardless of whether they are accredited, should be reported where the payments exceed the threshold.

7. Reporting threshold

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

The RANZCP recommends that the threshold for reporting payments to individuals be set at $1,000 per year, as per the National Health and Medical Research Council for people appointed to NHMRC committees.

Reporting $25 or $100 aggregate payments will lead to a large database of small figures, which may obscure larger payments to practitioners that may be of greater public interest. Reporting of small figures can reduce the potential behaviour-change impacts of this model.

The next edition of the Code of Conduct should include reports of payments or transfers of value to hospitals, health services, health care professional associations, non-government organisations, and universities.

7.2. What time period needs to be allowed for companies to implement mechanisms to record and report information? Does this differ depending on the thresholds set, or not?

Companies need adequate time to record and report information irrespective of the thresholds set.

7.3. What are the risks associated with setting the threshold too high or too low?

Setting the threshold too low will lead to a high level of administration costs for little return.

7.4. 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?

Function costs should be published but not distributed among delegates or attendees at meetings. Distributing these costs amongst the delegates or attendees could attribute expenses to individuals who may have opted out of pharmaceutical-provided sessions or lunches and give an inaccurate impression of the attendees, unless clearly worded. The use of ‘distributed’ and ‘non-distributed’ sections in the reports could serve to clarify this.

7.5. 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?

Changing the threshold along with the CPI is appropriate.

8. Clinical research

8.1. Does Section 5.3 adequately describe and define clinical research activities?

The RANZCP notes that the transparency model proposes that the reporting payments associated with clinical research are not required. However, the explanation under Section 5.3 does not adequately describe and define clinical research activities and this is of concern.

There is need to address the relationship between health care 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. The RANZCP notes that the Transparency Model includes the role of key opinion leaders and other similar relationships (such as advisory boards and consultancy). However, one of the most costly elements of this relates to research. Clinical research should be included in the transparency model. All payments above the threshold that are made to individual researchers, or research institutions, including hospitals, should be publicly reported. This would better enable doctors and other health professionals to interpret the research outcomes while taking into account their funding sources. This will increase transparency in the relationship between companies and health care professionals.

In 2010, pharmaceutical companies in Australia reported a total expenditure on research of $637 million across 2,107 studies. Sixty per cent of that research was conducted in public hospitals, 15% in private research institutes and 12% in private hospitals. The Transparency Model should include reports of the funding provided to hospitals and universities; important partners in the research process.

9. Starter packs

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

The RANZCP believes that starter packs should not be included in the Transparency Model – such products should be abolished entirely. Drug samples are a very important category of gifts. In the United States in 2005, the pharmaceutical industry gave away samples with an estimated retail value of over $18 billion, representing 11.2% of sales. An industry survey of US doctors reported that samples influenced their prescribing more than any other promotional activity. The market for pharmaceuticals is different in Australia, but samples are still an important influence on doctors prescribing behaviour.

10. Payments for expert witnesses in legal or administrative proceedings

10.1. 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?

Reporting requirements should not exempt expert witness paid by pharmaceutical companies, regardless of the Procedural Rules of Court. The relevant Expert Witness Code of Conduct for each jurisdiction is sufficient for these purposes.

11. Procedures for electronic submission of reports

11.1. What are the advantages and disadvantages of these different options for who should receive and publish the reports? Are there other options that should be considered?

The RANZCP has no comment on the different options for who should receive and publish the reports. However, appropriate resourcing will be required for the organisation that undertakes this work.

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

The RANZCP recommends the AIHW undertake this work. Please see responses 2.1 and 2.2 for further information.

11.3. Is the timeframe for submitting the reports by 31 May each year appropriate, taking into account Section 7.3 which suggests a mechanism to allow each healthcare professional to review and verify payments and transfers of value attributed to them?

The timeframe of 31 May each year is insufficient. The RANZCP recommends a timeframe of by 31 September each year to give practitioners time to provide the necessary information.

12. Timeframes

12.1. Is the timeframe for reviewing the information appropriate?

The practitioner may not have enough time in a month and a half to review the information. Three months is a better option.

12.2. Do you have any suggestions for how this process could be streamlined or facilitated?

The data should be available online for practitioners to access. The data should be password-protected.

A clear process is required to ensure that incorrect data is rectified as soon as possible. Where data is incorrect, a company should have an email point of contact to attend to inquires from health professionals.

13. Data disputes

13.1. Is this procedure fair and appropriate?

No. Publishing and leaving incorrect data online is inappropriate, even if it is only for a matter of months.

13.2. 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?

A clear mediation process is required to ensure that only accurate data is published and remains on the website.

14. Updating the information

14.1. Do you think that there should be a period after which historical information is removed from the website; for example, after five years?

Five years is appropriate.

Additional comments

- Clarification on Medicines Australia's position on transparency in investment in companies is required. For example, if a medical practitioner's superannuation fund manager invests in a pharmaceutical company without the practitioner's knowledge, does this have implications for transparency reporting?
- Medicines Australia should outline differing penalties for different types of breaches. For example, if a medical practitioner fails to report receiving a meal from a pharmaceutical company at a function, does this hold the same weight as those who are paid by pharmaceutical companies to speak at events?