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

Dear Secretary

Thank you for the opportunity to contribute to the review of the Medicines Australia (MA) Code of Conduct (the Code).

The AMA supports increased transparency measures in addition to those already voluntarily undertaken by Medicines Australia.

The AMA also recognises the increasing perception of patients that industry payments may be influencing their medical practitioner's treatment decisions.

It is critical that careful thought is given to the development of a model for reporting industry payments to individual practitioners.

The AMA considers that a 'successful' reporting model should:

- provide information to enable patients to make well-informed decisions about their healthcare options taking into account the context and nature of their practitioner's involvement with companies;

- not deter or constrain legitimate and ethical relationships between pharmaceutical companies and medical practitioners, as governed by industry and professional codes of conduct; and

- provide value to patients while balancing the red-tape and resource impact on companies and practitioners.

These principles should guide all decisions about the reporting model's characteristics and how it operates.

Throughout the many stakeholder forum discussions and public commentary, proponents of full reporting of payments to individuals have called for the wholesale adoption of the USA 'Sunshine Act' model. The proponents have neglected to recognise that the model

operating in the USA is a legislated model introduced and implemented by government. The model introduced in Australia will be voluntary and implemented by MA members. A wholesale adoption of the USA model could have the effect of companies withdrawing from MA membership due to implementation costs and the difficult timeframe imposed by the ACCC. This would be a serious retrograde outcome, given the impact that the MA Code of Conduct has had over its 17 editions to stamp out unethical industry activities.

There are clearly many issues to be worked through to ensure that the information collected by companies and the transfer of that information to MA for public reporting meet the various requirements of the *Privacy Act 1988*.

The AMA considers it necessary that MA obtain legal advice to ensure the reporting model that is submitted to the ACCC complies with the Act. Such advice may identify the need to limit the scope of the model.

On balance, the AMA therefore encourages MA to consider, as a first step, implementing a smaller-scale and more achievable reporting model than the one proposed in its Transparency Model Consultation and Discussion Paper.

Rather than recording and reporting all payments/benefits provided to practitioners over a certain amount, the model should focus on:

- Consulting fees – for consultancy services provided to a company
- Speaking fees – for speaking at, or chairing, events
- Sitting fees – for serving on company advisory boards or committees
- Sponsorship to attend an event – covering registration fees, travel, accommodation.

These categories are consistent with the ACCC's final determination of December 2012 which stated that '*there is merit in providing greater transparency around the sponsorship provided to healthcare professionals by pharmaceutical companies to attend educational events*' (paragraph 153). It appears the ACCC only '*expects Medicines Australia to incorporate new provisions in the Code that will facilitate greater disclosure around sponsorship and fees paid to individual doctors*' (paragraph 158).

Not only is it likely that the above payments will be of more interest to patients than 'tea and biscuits' benefits, but this approach would vastly decrease the administrative burden on both industry and practitioners of recording, verifying and reporting all interactions.

In addition, MA already publicly reports on these payments in aggregate.

The AMA recommends any new reporting model be evaluated after two or three years to examine how the database is used and its value to patients. Based on the evaluation of results, MA could then reconsider moving to a reporting model that includes further categories of payments, such as those currently proposed.

Nevertheless, the AMA has provided detailed comments at Attachment A on the proposals made in the MA discussion paper including those proposals relating to payment categories and thresholds for recording and reporting. Our comments are guided by the principles identified above.

Finally, the AMA notes that the proposal it made in its submission to MA in 2011 during the review of the previous Code was not adopted. Section 9 of the current Code – *Relationship with healthcare professionals* – should require that all educational event promotional material include a statement from the company that the event complies with the principles of the Medicines Australia Code of Conduct. This would strengthen the application of the Code and provide clarity for medical practitioners on this aspect, particularly as medical practitioners attending these events could now be individually named.

Please contact Georgia Morris, Senior Policy Advisor, on 02 6270 5466 or at gmorris@ama.com.au in the first instance.

Yours sincerely

Dr Steve Hambleton
President

24 September 2013

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Attachment A

AMA COMMENTS ON MA DISCUSSION PAPER AND PROPOSED REPORTING MODEL

Scope of health professionals

The AMA supports the application of the reporting model to all health practitioners involved in prescribing, dispensing, supplying, recommending and administering prescription medicines.

Definitions

Healthcare professional

The AMA is not aware that the *Therapeutic Goods Act 1989* provides any definition for the term healthcare professional, as asserted in the discussion paper. The definition would be more accurate if it read: 'Health professional' includes any healthcare practitioner that is authorised under State/Territory law to prescribe, dispense, recommend, supply or administer a prescription medicine in Australia.

Direct and indirect payments

The definitions should clarify that these refer only to the payment categories listed under clause 3.7 of the discussion paper.

Management of reports

MA should receive, manage and publish the report on payments to individual practitioners as it currently does for aggregate payments.

These reports are concerned with increasing the transparency of pharmaceutical company activities in accordance with the MA Code of Conduct. Therefore MA is the most appropriate body to carry out this task.

The cost of aggregating, managing and publishing information must be borne by industry.

If the scope of reporting widens in the future beyond pharmaceutical companies then consideration can be given at that time about the most appropriate entity for this role.

Information to be reported

The AMA supports the proposed information to be reported and excluded in the discussion paper with the following exceptions.

Unique identifier

The AMA opposes use of the practitioner's AHPRA registration number.

The AHPRA registration number is a number allocated to health practitioners for the purpose of regulating health practitioners. It is not appropriate to associate the use of that number for the purpose of regulating the activities of pharmaceutical companies. Use of the number risks implying a link to the regulation of health practitioners, which is not the purpose of public reporting of pharmaceutical company payments.

The AMA considers that use of the AHPRA registration number may contravene clause 7.1 of the *National Privacy Principles* which state that 'an organisation must not adopt as its own identifier of an individual an identifier of the individual that has been assigned by an agency'. A unique number can be generated specifically for the purposes of the MA Code of Conduct and in order to run the database.

Further, it is not necessary for any unique identifier to be published. There is no reason why any additional information is necessary. There is sufficient variation to identify the correct practitioner by using the practitioner's name and location of practice.

Clinical context field

The AMA considers there should be a field that indicates the clinical issue and/or product (e.g. diabetes management, cardiovascular disease) most relevant to the relationship, in addition to the payment categories already identified.

As well as enhancing trust in the doctor-patient relationship, this information will assist patients in making informed decisions in relation to their individual clinical care. Without information on the nature and context of the relationship, patients are unable to determine whether the relationship between the practitioner and the company is relevant to their personal circumstances.

For example, a practitioner's attendance at an educational seminar funded by a pharmaceutical company about asthma medications will not be relevant to a patient seeking care for hypertension. Alternatively, a practitioner's sponsorship by a pharmaceutical company to attend an international conference on the treatment of a rare disease may be relevant to a patient seeking treatment for that specific rare disease. The patient may be reassured that their practitioner is up-to-date on treatments found to be effective in larger, international populations.

The importance of this information was recognised in the USA. The 2013 general payments template issued by the USA Centers for Medicare and Medicaid Services, which must be used to report physician payments under the Open Payments Program (enacting the 'Sunshine Act' provisions), provides two fields that help ensure that sufficient information is provided to patients about the context of the payment:

- a compulsory field naming the associated drug or biological (up to 5 products)

- a voluntary 'contextual information' field where the physician can enter any free text which is helpful or appropriate regarding the payment or transfer (up to 500 characters).

Recording and reporting thresholds

The AMA considers it is sensible to take a practical approach and set thresholds based on pragmatic reasons given that there is no evidence yet available to support specific threshold levels, nor about the impact to patients of public reporting. Thresholds can always be adjusted once the reporting model has been in place for a time and we have more experience of its use and benefits.

In addition the model should be realistic about the resources that will be required to report all payments and the red tape burden this would impose on both companies and practitioners. For example, the MA educational events report for October 2012 – March 2013 covered 346,474 practitioner attendees.

The AMA therefore supports a combination of both threshold options proposed in the consultation model.

- The <u>recording</u> threshold should be $25.

Setting the recording threshold at $25 should capture all significant payments to practitioners. The administrative costs of recording all interactions under $25 will be high. The administrative onus falls not only on pharmaceutical companies but on every individual practitioner to accurately record interactions so that they can later review and certify information to be reported is correct.

- The <u>reporting</u> threshold should be $500.

Again, this amount represents a pragmatic approach ensuring that significant payments are reported for the information of patients. The USA model sets the reporting threshold at $US100 (approx $108) while the Dutch model sets the threshold at 500 euros (approx $718).

The thresholds should be indexed annually using the consumer price index which should provide a reasonable reflection of increases in travel, hospitality and similar costs.

Allocation of non-hospitality/non-travel function costs

The AMA does not support the allocation of costs, such as audio-visual and room hire costs, to individual practitioners. The pharmaceutical company would incur these costs whether or not the individual practitioner attended. There is no direct benefit to the

individual. It therefore is inequitable and as well as meaningless for patients to apportion these payments to individual practitioners.

Inclusions/exclusions

The AMA supports the proposed inclusions and exclusions except for the following.

Clinical research payments

The AMA is aware that there is also a perception that pharmaceutical companies influence the conduct of research and its results through funding. While it may be difficult to define and identify individual practitioners as recipients, given funding is generally made indirectly to an organisation, the reporting of these payments should be further explored.

Business to business trading arrangements

It is not clear to the AMA what these arrangements cover and why they should be excluded if they involve a pharmaceutical company and an individual practitioner. The AMA does not support this exclusion based on the information provided in the consultation paper.

Governance arrangements

The AMA supports the proposed governance arrangements in general. (As noted on page 2 of our submission, MA should seek legal advice to ensure these arrangements comply with the *Privacy Act 1988*.)

However, the AMA seeks clarification about which specific information MA intends that practitioners will review and certify. Practitioners will be able to check that information such as their name, practice address, date of payment, form of payment and category of payment is correct but will not be able to determine whether the amount of payment or transfer of value is correct except in a minority of situations.

For example, a practitioner may be able to confirm that he/she received a sitting fee of a specific amount for participation in an advisory committee on a certain date. However it will not be possible for a practitioner to confirm that the allocation of a transfer of value resulting from attendance at an educational seminar is correct when it has been calculated by the sponsoring pharmaceutical company based on its costs per head.

The process for practitioners to review, correct and dispute information is supported, with the addition of a mechanism for practitioners to remove information if it has been incorrectly attributed to them.

There should be at least two opportunities each year to update the report with corrected information.

The AMA considers that information on the report should remain public for two years. Information older than this will not be useful to patients making decisions about their healthcare options today.

Operational issues

There are several important operational issues not covered in the consultation document that will improve the outcomes of the report. These are issues that should be debated in MA's consultation process. While they may appear administrative in nature, they are significant to the successful implementation of the model, measured against the principles we identified at the beginning of our submission.

Users should understand the purpose of the database and context of the information

The public report website should require users to read and acknowledge a statement before they can access information that explains the benefits to clinical care of medical practitioner engagement with pharmaceutical companies.

In addition the statement should explain that the listing of an individual's name does not imply any unethical or inappropriate behaviour and occurs in the interests of transparency only.

The statement should recommend that users talk to their practitioner to gain a better understanding of the nature and context of the relationship.

A similar 'step' is required before users can access the TGA's adverse reactions database. For example, users must acknowledge they understand that listing of an adverse reaction does not imply causality.

Users should only be able to search the database for the purpose of informing their healthcare options

Information should only be available by entering one practitioner's name at a time, consistent with patients looking up information about a specific practitioner. Therefore the only search criteria should be the practitioner's name, refined by suburb and postcode of place of practice. Public access to the information in any other way is not consistent with the purpose of assisting patients to make informed healthcare decisions.

The reporting model should be evaluated

An evaluation should be conducted after three years to determine how patients use the information and any consequential benefit to them. An evaluation will enable the reporting model to be measured against how well it meets the principles identified at the beginning of our submission.

The model should be refined based on the findings. Public reporting should not continue if the costs of reporting outweigh the, as yet, unquantifiable benefits to patients.

Users should register to allow effective monitoring and evaluation of benefits

Users of the public report should be required to register by providing an email address and an indication of user category, e.g. patient, health practitioner, researcher, journalist, government employee, pharmaceutical company, professional organisation, industry organisation.

This is the minimum information required to enable a useful evaluation of the model and inform future refinement. The category information will allow an assessment of how many individuals are using the database (as opposed to how often it is accessed) and how many of these are patients. Email information will allow evaluators to contact users and seek permission to ask questions about how they used the database and whether the information was useful to them. Users could indicate at registration whether they agree to be contacted in this way.