The Royal Australian College of General Practitioners

RACGP Submission to Medicines Australia

Medicines Australian Code of Conduct Review - Transparency Model Consultation and Discussion Paper

RACGP details

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1. Introduction

The RACGP commends Medicines Australia for inviting a range of interested parties onto the Transparency Working Group (TWG) and for producing a discussion paper which reflects a balanced summation of where these parties agreed and disagreed.

This response has been drafted by the RACGP representative on the TWG, Dr Justin Coleman, and is endorsed by the RACGP Council.

2. Summary

Overall, the RACGP supports the discussion paper, with the specific provisos that in section 5.2, Alternative 2 is selected for *Reporting thresholds*, and also that the cost attributed to each doctor attending a sponsored event does include the full cost of that event (i.e. includes non-hospitality and non-function costs).

3. Responses to each discussion box (numbered according to their order of appearance)

Box 1: Glossary

The glossary is adequate as it stands.

Box 2: General Requirement & Limitations: Scope of the transparency model

i. We believe that the transparency model should apply across various industry codes. We understand that this is beyond the remit of the current model, but we would support any initiative which might broaden the application of the code into two other areas.

First, although members of Medicines Australia (MA) supply the majority of prescription medicines on the PBS, a substantial proportion—particularly generic brands—are supplied by companies who are not MA members. We would urge legislators and the ACCC to obligate the Generic Medicines Industry Association (GMiA) to include the same model in their code. We recognise that the transparency code will require considerable start-up and ongoing costs for MA member companies, and it therefore seems unreasonable that GMiA members should be advantaged if they avoid all costs of complying with the transparency code, and consequently their payments to doctors are allowed to remain hidden.

Second, we believe this code should also serve as a template for an obligatory code applying to members of the Medical Technology Association of Australia. The details may vary to some degree; some medical devices require specific instruction as to their use, and the manufacturers play some legitimate role in providing this advice. However, transparency does not prevent this process; it merely improves its availability for public scrutiny.

ii. The discussion paper asks the question whether MA or an independent body should bear responsibility for receiving and publishing transparency reports.

In the longer term, we believe it would be more practical for an independent, federally funded body to manage this process. This would then facilitate the expansion of similar transparency codes into areas of industry outside the remit of MA, as described above. Indeed, in the case of GMiA members, it would clearly be inappropriate and a conflict of interest for MA to manage their transparency data.

However, we recognise that setting up and maintaining this transparency process requires significant financial outlay. We believe this cost should be borne by the industry to which the code applies; in the first instance, this is the MA membership.

Therefore, we suggest a consultation process to investigate the practicalities of an independent body setting up the system and invoicing MA for the cost, or MA setting up the system on the understanding that the responsibility may in future be 'passed on' to an independent body.

Box 3: Identifiers for health care professionals. (3.3)

We recommend that the AHPRA unique identifier be used for collection of data.

This identifying number is already in the public domain, and it circumvents potential problems of matching each pharmaceutical company's system for identifying the doctors with whom they have dealings. To create and continually update a new unique identifier just for the transparency system would be a redundant waste.

We cannot envisage any practical disadvantage of using this system for doctors, all of whom are already obliged to have an AHPRA identifier.

Box 4: Category of payment or transfer of value. (3.7)

We agree with the recommended categories.

Box 5: Payments to third parties, including registered charities. (3.8)

We agree with the wording as it stands.

Box 6: Requirements for payments or other transfers of value related to continuing professional development programs. (4)

We agree with the wording as it stands.

We understand that some large educational events run by doctors' organisations choose to allow sponsorship and display tables by pharmaceutical companies. The important proviso here is 4.1c, which ensures that the choice of educational topic and speaker is made by the independent conference organisers and is not influenced by the sponsor.

This exemption 4 recognises that it would be both unreasonable and impractical for the sponsorship payment to be attributed to some or all of the doctors who attend the conference, or doctors who are invited to speak at the conference.

Box 7: Reporting threshold (5.2 i)

We support Alternative 2 for 5.2 i

I.e. For calendar year 2015, payments or other transfers of value less than $10 do not need to be recorded or reported. Payments or transfers of value of greater than $10 must be recorded but do not need to be reported unless the aggregate amount paid or transferred to the healthcare professional recipient exceeds $100 in a calendar year.

We believe it is appropriate that if a doctor accepts payment (or transfers of value) of more than $100 from the one pharmaceutical company in the one calendar year, then this should be recorded on the transparency register. We accept that, for practical reasons, it is reasonable to exclude the requirement to record payments valued at less than $10.

We note that this transparency model in no way restricts the doctor accepting such payments; it merely serves to make the payments transparent. A doctor who wishes to avoid their name ever appearing on the transparency register may still accept an unlimited number of payments of less than $10, and also accept up to $99 from any number of pharmaceutical companies in each calendar year.

We do NOT support Alternative 1 for 5.2 i

For calendar year 2015, payments or other transfers of value less than $25 do not need to be recorded or reported. Payments or transfers of value of greater than $25 must be recorded and reported.

We believe that the distinction between Alternatives 1 and 2 impacts on GPs more than any other group of doctors, and so we take particular interest in the wording of this section5.2.

GPs account for the largest group *by volume* visited by pharmaceutical representatives, although the amount spent *per doctor* is smaller than for the medical specialties. We believe that an exemption for recording payments less than $25 will result in the overwhelming majority of visits by pharmaceutical reps

to GP surgeries 'flying under the radar'. This potential loophole is large enough for this type of interaction to remain virtually unrecorded.

Given the ability to divide the per capita cost during a surgery visit by the number of people who partake in lunch (or similar), one can imagine that it would be easy to ensure the catering costs fell to $24 or less per head. It also appears that non health-professionals may be included in the denominator; there does not appear to be any clause which would stop, for example, a $95 lunch for two doctors and two practice nurses or other staff being divided by four, which would therefore go entirely unrecorded against the doctors' names, even if the same company provided lunch on a regular basis.

Alternative 1 would be considerably cheaper for industry compliance because the majority (in number, not value) of doctor payments would be exempted. This Alternative 1 would make the recording tasks for pharmaceutical reps far easier—virtually non-existent as far as GP practice visits are concerned—but could defeat one of the main purposes of the transparency system.

After all, a large part of the public benefit deriving from the transparency code rests on improved insight into interactions between doctors and pharmaceutical representatives who are promoting one particular therapeutic product over another. The higher $25 recording threshold would still capture payments to speakers and 'key opinion leaders', but would miss most of the smaller payments, which nonetheless are known to influence prescribing patterns.

Sunshine Act comparison:

We note that our preferred Alternative 2, which is the more stringent of the two proposed alternatives, is still *less stringent* than the equivalent section of the US Physician Payments Sunshine Act. This is because the US $10 threshold exempts only reporting, whereas our Alternative 2 $10 threshold exempts both recording and reporting.

In the relevant part of that Sunshine Act, the *Exclusions from reporting* section states:

> *The following are excluded from the reporting requirements specified in this section...*
>
> *(2)(i) For CY 2013, payments or other transfers of value less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds $100 in a calendar year.*

In other words, the Sunshine Act does not have any lower limit for recording payments. It requires that even amounts below $10 must be recorded, and count towards the aggregate $100 reporting threshold. Our Alternative 2 releases the pharmaceutical company from the obligation to collect any data regarding payments under the $10 threshold. We believe this is a fair compromise.

This distinction between what the $10 refers to in the Sunshine Act and in this proposed Australian code, is one which has already been ignored in some medical

media reports. The RACGP member on the Transparency Working Group felt that it was poorly understood during discussions, and may possibly creep in as an errant assumption in other submissions regarding this discussion paper.

However, it is important to note that the distinction will undoubtedly exist if Alternative 2 is chosen.

5.2 ii

(ii) Payments or other transfers of value of greater than $10 in calendar year 2015 provided at large-scale conferences and similar large-scale events, including events open to the public, do not need to be recorded nor included in the $100 aggregate threshold in calendar year 2015 even if the aggregate total for an individual healthcare professional exceeds the aggregate threshold for the calendar year.

Regardless of whether Alternative 1 or 2 is chosen, we suggest clarifying the phrase '*large-scale conferences and similar large-scale events'* in this section. Presumably these are distinct from the educational conferences described in section 4 (see our comments in Box 6, above) and refer to events such as a public 'Expo'. However, we would be concerned that the current wording might allow a pharmaceutical company to arrange an event such as an expensive conference in an exotic location, justifiably call it 'large-scale', and thereby gain an exemption.

Unless we misunderstand the intent, perhaps the same three restrictions as apply in 4.1 (a,b,c) should also apply here. This point would benefit from further clarification.

We also note that the phrase '*of greater than $10 [or $25] in calendar year 2015'* is superfluous in both Alternative1 and 2. This is because the exemption is describing a situation which applies regardless of any particular monetary value, and thus no threshold is relevant.

Box 8: Non-hospitality and non-travel function costs

We believe that all costs involved in an event that is paid for by a pharmaceutical company should be included in the calculation of transfer of value. In other words, the code should not allow an exemption for non-hospitality costs.

When a doctor turns up to a dinner or day-long event organised by the RACGP, Medicare Local or hospital etc., the event involves not only the food they eat, but the costs of the whole function, including room hire, audiovisual equipment, entertainment etc. No organiser would calculate their required budget based only on a meal cost unless that is truly the only cost involved. In cases where the event is not subsidised, the doctor will be informed of the overall cost of attending that event.

In the same way, if a doctor chooses to attend a pharmaceutical dinner or event, the amount spent on that doctor is a per-capita proportion of the total event cost,

not just the food cost. These costs will already be calculated in any case by the company in allocating a budget for the event. We suggest that the 'attendance cost' should be made known to the doctor prior to the event. The difference in this case is that the doctor does not need to pay any money, but will instead know the amount which (if over $100) will be recorded against their name on the transparency register.

We have concerns that if non-hospitality costs are exempted, particularly if Alternative 1 is chosen with the $25 recording threshold, then some venues might quickly learn to cost-shift their event charges, such that hospitality costs are reduced to $24 per capita, and other venue costs are increased proportionately.

Box 9: Clinical research (5.3)

Section 5.3 adequately describes research activities.

Box 10: Starter packs

We believe starter packs should be excluded from being part of the recording or reporting requirements.

Current law already clearly prohibits doctors selling these packs. Any transfer of value does not flow to the doctor, but to the patient. Upon receiving a 'free sample', the reasonable patient would already be aware that the manufacturer of the product has supplied the starter pack.

Box 11: Payments for Expert witness in legal or administrative proceedings

We believe that payments to healthcare professionals acting as professional witnesses should be excluded from reporting requirements.

Although it is likely that a pharmaceutical company will choose an expert witness whom they hope will be more likely to give a favourable opinion, the law does require that the expert's duty is to the court rather than to the party involved. Depending on the length of the testimony, these payments can sometimes be quite substantial, but it is inappropriate that they would be recorded on the transparency register.

Box 12: Procedures for electronic submission of reports (6)

The responsibility for submitting timely, accurate reports must lie with each participating pharmaceutical company. Their reports must be submitted in the appropriate format, ready for 'slotting in' to the publication system. Appropriate penalties should apply if this process is not completed. Each company will also be

responsible for the resolution of any disputes as to whether an individual doctor actually received the stated payment or transfer of value.

The responsibility for actually publishing the submitted data and for maintaining the website should lie with whatever body is delegated that task. As we discussed above (Box 2 ii), this may well be Medicines Australia in the first instance, although eventually perhaps AHPRA or another delegated body.

Box 13: Timeframe (7.2)

We feel that the suggested timeframe of 45 days for the doctor may be too short. We would suggest two months.

Box 14: Data disputes (7.4)

The process and timeframe for data disputes appears to be fair and appropriate.

Box 15: Updating the information

We feel that a five year 'sunset clause' is appropriate, requiring the removal of old data after that time.

Thus, eventually, only the most recent five years of data would be available for public viewing.