



*RACGP Submission to Australian Competition
and Consumer Commission (ACCC)*

Medicines Australia Limited application for revocation of
authorisations A91316 – A91320 and substitution of new
authorisations A91436 – A91440

30 July 2014

The Royal Australian College of General Practitioners

RACGP details

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The RACGP

The RACGP is Australia's largest professional membership body for general practitioners (GPs). With over 26,000 members across Australia, the RACGP works to support the profession through defining the standards for quality care, developing guidelines and resources, delivering education and training and advocating on behalf of general practices and general practitioners to promote the importance of a safe, quality and holistic approach to patient care.

This submission has been prepared by the RACGP with significant input from Dr Justin Coleman, RACGP representative on the Medicines Australia Transparency Working Group.

Introduction

The previous Australian Competition and Consumer Commission (ACCC) 'Medicines Australia Limited Determination' stated:

Edition 17 of the Code incorporates amendments that are intended to: increase transparency around the interactions between pharmaceutical companies and healthcare professionals, third parties and patients – including requiring member companies to report on the sponsorship of healthcare professionals to attend or speak at educational meetings, and on any payments made to healthcare professionals to act on advisory boards or to provide consultancy services.

Edition 17 stated that this transparency should occur, but gave little indication as to how this would come about. In that light, the ACCC gave MA two years to come up with specific detail around achieving transparency.

MA then set up the Transparency Working Group (TWG), which involved relevant stakeholders including a consumer representative, and the RACGP, represented by Dr Justin Coleman. We note that the RACGP was mistakenly left off the list in Annexure 3 of the MA Edition 18 Code of Conduct submission.

Over a number of meetings, the TWG developed the [Transparency Model Consultation and Discussion Paper](#). The RACGP believes this document was a fair and accurate representation of the TWG deliberations and, where TWG members had significantly differing opinions, the document contained various text boxes with two alternative approaches for consideration.

At the time the TWG was dissolved, the RACGP was comfortable with the process and the resultant discussion paper, published on 21 June 2013.

Events post Transparency Working Group

Subsequent to the discussion paper, MA asked for public comment and received [85 submissions](#). MA then set up a Code Review Panel, consisting of one consumer representative (Dr Ken Harvey), one AMA representative and 13 pharmaceutical representatives. This panel ostensibly was tasked with distilling the original discussion paper and 85 submissions into an MA Transparency Model, which forms the basis of their Edition 18 submission.

We submit that this Code Review Panel failed in its task. The [summary of the MA Transparency Model](#) differs from the original TWG discussion paper so profoundly that the RACGP wonders if the TWG and

subsequent public discussion had the primary aim of 'being seen to consult', rather than serving as any meaningful consultation process.

It appears that the Code Review Panel rejected or altered proposed new changes that would have promoted transparency. Specific details are discussed in the next section.

MA presented the latter document at its Stakeholder Forums in Sydney and Melbourne (28-29 April 2014), and a webinar (23 May 2014). It is our understanding that the stakeholders at those meetings were not presented with the original TWG document, were not made aware that multiple significant changes had occurred, and crucial debates at the TWG were not discussed, as they had been left out of the newer document altogether.

It appears from April 2014 onwards, any public consultation and ratification of the Stakeholder Forums were based on a one-sided view reflecting the pharmaceutical industry's preferred position, but were presented to stakeholders as being the view of the TWG and the 85 submissions.

The MA Edition 18 application to the ACCC claims:

As a result of this ongoing consultation, Medicines Australia is confident that it is proposing a transparency model that is workable, effective and enjoys broad support from its members, the health sector and consumers. (Sec 5.3, p15, underlining added)

Claiming broad support is unjustifiable when the TWG's deliberations and recommendations have been ignored.

The RACGP representative raised this objection with all members of the now-disbanded TWG via email on 13 May 2014, as soon as he received the summary document (sent to him not as a TWG member, but in another professional capacity). This started a series of concerned emails among the non-pharmaceutical-industry members of the group, some of whom had not seen the document. There was general consensus among all those members who replied, that the document being shown for approval at Stakeholder Forums differed fundamentally from the TWG document; this consensus was conveyed to Ms Deborah Monk, Director of Compliance at MA and TWG secretariat.

Specific differences between the TWG document and the MA Edition 18 proposed amendment

In this section:

'TWG document' refers to the [TWG Transparency Model Consultation and Discussion Paper](#)

'MA Edition 18' refers to the [MA Detailed Summary of Amendments Included in Code of Conduct Edition 18](#)

Visiting pharmaceutical representatives ignored

A great deal of the discussion at the TWG involved the possible ways of capturing some data around doctors who see large numbers of pharmaceutical representatives at their surgery. This is one of the central tenets of the US Sunshine Act, and also arguably causes the largest burden in data collection for pharmaceutical companies, because although the payments-in-kind are small in individual dollar terms, they

are very large in volume, and all of them must be recorded under the Sunshine Act, with no minimum recording threshold.

TWG members felt it was more practical to have a minimum reporting threshold, under which the pharmaceutical rep did not have to record doctors' names. Two possible recording thresholds were proposed, being \$10 and \$25:

A recording threshold of \$10 would capture lunches provided in a medical practice, for example...

Other members of the TWG considered that the proposed reporting model should have a \$25 threshold for recording and reporting payments... These members were concerned at the complexity of capturing low level hospitality provided by sales representatives at the individual healthcare professional level. Company Chief Financial Officers (CFOs) had advised the TWG that most companies would have to build new systems to capture these data, whereas their current systems could capture and report payments or transfers of value above \$25. Systems being implemented in the US to comply with the US Sunshine Act are not easily "imported" into Australian companies because the same software platforms are not used universally by a company's country affiliates.

The transparency model for consultation therefore includes both options for consultation. (TWG document, p9)

The lower \$10 threshold caused considerable stir in the medical media, and a substantial number of the 85 submissions called for the higher threshold.

However, *MA Edition 18* makes no mention of any mechanism for recording any such interaction with visiting pharmaceutical reps. This document - presented at Stakeholder Forums, and the basis of the 'broad public support' claim - fails to raise visiting pharmaceutical reps as an issue at all; does not note that it was ever discussed; nor provides any possible mechanism allowing such interactions to be recorded. Although even the \$25 option, preferred by TWG pharmaceutical members, gave more leeway than the \$zero recording threshold in the Sunshine Act, the entire concept was wiped from *MA Edition 18*.

Monetary threshold of \$120

The back-and-forth TWG debate around the \$10 vs \$25 recording threshold affected more than providing some transparency around visiting pharmaceutical reps. The \$25 threshold, while it may have missed the majority of lunches provided to doctors at their surgery, was likely to capture attendance at more substantial marketing events such as 'educational dinners' at restaurants.

Transparency in the public interest would seem to imply that health professionals who choose to receive payment-in-kind via restaurant wining and dining, repeatedly throughout the year from the one pharmaceutical company, should expect to have that fact made publically available.

However, *MA Edition 18* has set the recording threshold amount at \$120. No reason is given for this arbitrary figure, and this year's Stakeholder Forums attendees were given no indication that the \$120 figure was not even considered at the TWG – it is five times the maximum suggested TWG figure.

Single event recorded, but annual total ignored

The TWG recognised that the \$10 threshold for recording an interaction should only require reporting when the annual total reached \$100:

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. (TWG document, Alternative 2, 5.2 i)

The \$25 alternative option was felt to be reasonable as both a recording and annual reporting threshold.

Every option considered by the TWG, including those proposed by invited presenters from the pharmaceutical industry, understood that, as a doctor accumulated more and more payments-in-kind on individual occasions throughout the year from the one company, they would eventually cross a monetary threshold at which reporting would occur.

However, *MA Edition 18* section 9.4.3 states:

Inclusion of a maximum limit of \$120 (excluding GST and gratuities) for the cost of a meal (including beverages) provided by a company to a healthcare professional within Australia.

The wording *'for the cost of a meal'* indicates that this is a once-off reporting, and that no amount smaller than \$120 will ever accumulate towards an annual total. It also, seemingly randomly, excludes GST, so the \$120 in everyone's discussion should actually be \$132.

To use an extreme example, theoretically a health professional could have three lavish meals provided every day, totalling tens of thousands of dollars per year from the one company, and nothing need ever be recorded unless the cost of one of those meals exceeded \$132. Even then, only that single meal cost need be recorded against their name. This is obscurity rather than transparency.

Non-meal costs are excluded

The TWG document explains the discussion:

Another important issue for discussion is whether non-hospitality and non-travel function costs should be allocated as a transfer of value to the healthcare professionals who have attended an educational meeting. That is, audio-visual and room hire costs etc. could be distributed between attending healthcare professional delegates. Whilst some TWG members thought that these costs should not be allocated to attendees, it was also strongly argued by some members that all costs of an educational meeting should be allocated to the attendees. This view was in part due to a concern that there could be 'cost shifting' of food and beverage costs to non-reportable function costs in order to stay below the threshold for recording and reporting hospitality and other costs.

This discussion particularly applied to the circumstance in which the higher of the two (\$10 and \$25) proposed thresholds was chosen, because it was felt that most function centres would be able to invoice pharmaceutical companies such that the meal and beverage costs would be kept below \$25, and other costs (room hire, staff hire, AV equipment etc.) could make up the deficit.

Even after raising this threshold to \$132, *MA Edition 18* chooses to specifically exclude all non-meal costs:

9.3 – Educational Events

A new requirement that Companies must have policies and procedures in place that will ensure that educational events for healthcare professionals comply with the Code, and in particular, the maximum cost of a meal stated in Section 9.4.3.

Consider for a moment what the public might understand by transparency of pharmaceutical companies influencing health professionals. A health professional attends a weekend in a five-star hotel, with multi-modal presentations, entertainment, cocktails, promotional speeches, fine wining and dining, and yet nothing needs be recorded under ME Edition 18 because no meal is invoiced at more than \$132.

Although the circumstances are different (in that Advisory Board costs are currently made transparent), to highlight the significance of exempting non-meal costs, look at the published cost breakdown of current pharmaceutical events. These suggest that the Edition 18 non-meal exclusion could actually exempt 95% of the hospitality costs of running an event.

In a Pfizer Australia [document](#) published on the MA website: of the \$30,919 listed under 'hospitality costs' for 53 doctors (\$583 per head), not a single dollar would need to be recorded against any doctor's name, because the 'meals and beverage' component totals just \$1,677 – a mere 5% of the hospitality costs.

The whole transparency process is optional for the doctor

If the above four key loopholes in the *MA Edition 18* document conflicted with the intent of the TWG document, the inclusion of an opt-out clause for health professionals really questions the purpose and value of the whole document and TWG process:

- *If a healthcare professional does not agree to the [transparency reporting] information being disclosed with their name, the expenditure will be reported in aggregate with the number of healthcare professionals it relates to. (MA Edition 18, 4.1)*

Thus, even if the ACCC or any other entity was to negotiate on the other four key aspects, no health professional would ever have to see their name published. Indeed, given that transparency benefits the public good rather than the individual health professional, it is hard to envisage the public wanting anything but more transparency and the doctor-awaiting-publication wanting anything but less. This simple opt-out clause ensures that the health professional's preference is the only one obliged.

Summary of reasons for rejecting the Edition 18 amendments

The RACGP recommends that the ACCC does not authorise Edition 18.

The most basic reason for rejecting Edition 18 is that its transparency amendments do not actually provide transparency.

Additionally, the claims by MA that their submitted version of Edition 18 is the result of broad consultation are misleading. Adequate consultation did indeed take place, but then MA ignored it.

MA's claim that their submission 'enjoys broad support from the health sector and consumers' refers primarily to the original TWG document, which, as demonstrated above, is a fundamentally different document to the one subsequently offered to the ACCC.

The five 'inserted loopholes' reduce transparency in increments, starting from the smallest interactions between health professionals and pharmaceutical companies. Although the RACGP's initial [preferred position](#) was a \$10 recording threshold and a \$100 reporting threshold, to capture even the 'small stuff', we

would have been prepared to negotiate and accept a gradual approach if that were more practical and acceptable and in the end increased transparency.

In order from smallest to largest:

Payments-in-kind of under \$10 were never intended to be captured. A threshold of \$25 would have missed the majority of 'GP free lunches' but would have captured more formal dinners. However, the Edition 18 threshold of \$132 (advertised as \$120) will clearly fail to capture the majority of transfers of value. Thus, interactions between the average doctor and a pharmaceutical representative are at no risk of being made transparent.

If we consider more substantial interactions, 'Key Opinion Leaders' (KOLs) currently receive far more than average health professionals, yet they are under no obligation to declare any conflict of interest, and the public – including doctors in the audience – have no way of finding out about their payments unless transparency codes are applied. But Edition 18 allows KOLs to rely on the lack of any system requiring accumulation of costs over a year. As long as any payment-in-kind comes under the daily threshold of \$132, they do not need to declare, regardless of how many episodes occur in a year.

For KOLs that receive more than \$132 on any given day, Edition 18 has created the 'non-meal' exemption, which on current evidence of pharmaceutical reporting, allows about 95% of the hospitality costs to be listed as non-meals. Although it is unclear to the RACGP whether this degree of cost-shifting is possible under Edition 18, if it were, the daily hospitality threshold could in theory rise to above \$2,500.

Finally, there are some transfers that will need to be declared - International airfares and accommodation can't be hidden away as 'non-meal hospitality'. The pharmaceutical companies are indeed obliged to record these costs and now Edition 18 requires them to name the health professional, so that at least in this regard, transparency is increased. However, for these few unlucky health professionals, there is always the opt-out clause.

Alternatives to achieving transparency

The RACGP feels that discussing alternative pathways to transparency is beyond the scope of this submission. We have a firm view that current levels of transparency are inadequate for public protection, but accept that the ACCC is limited in the ways in which it can respond to Medicines Australia.

MA, in turn, is limited in that its Code of Conduct has to be acceptable to its members. The MA code's influence is limited, as it does not apply to pharmaceutical companies who are not MA members – notably GMiA members, but also companies who are not members of any umbrella organisation.

The current MA code does contain many features that enhance the public good. However, we believe that the proposed Edition 18 amendments will not actually enhance transparency, for the reasons stated above.

We feel that if the ACCC accepts Edition 18, even perhaps with some comment on the unsatisfactory aspects of the transparency model, then it sends the wrong message to MA and to the public that a lot has been achieved over the past two years and that, as MA CEO Brendan Shaw argues, "This new code sets new standards in the transparency in these interactions which is unprecedented in the Australian health sector."

Edition 18 may set new standards, but if so, they are too low.