

Allens

Deutsche Bank Place
Corner Hunter and Phillip Streets
Sydney NSW 2000 Australia

T +61 2 9230 4000
F +61 2 9230 5333
www.allens.com.au

GPO Box 50
Sydney NSW 2001 Australia
DX 105 Sydney

ABN 47 702 595 758

Allens < Linklaters

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Dr Richard Chadwick
General Manager, Adjudication
Australian Competition and Consumer Commission
23 Marcus Clarke Street
Canberra ACT 2601

Dear Dr Chadwick

Medicines Australia: Application for Revocation and Substitution A91436-A91440

This letter responds to the ACCC's request for a further submission regarding a potential authorisation condition requiring member companies to provide ongoing reporting of hospitality expenditure on an aggregate basis under Edition 18 of the Medicines Australia Code of Conduct (a **hospitality condition**).

1 Introduction

Medicines Australia submits that a hospitality condition should not be imposed in circumstances where:

- very significant public benefits will flow from Edition 18 of the Code;
- regarding transparency, Edition 18 of the Code involves a step change that will require reporting of information at an individual healthcare professional level;
- Edition 18 of the Code already provides detailed regulations regarding the provision of hospitality to healthcare professionals, including a new and absolute prohibition on providing hospitality that exceeds \$120; and
- aggregate reporting would provide very little, if any, benefit to the public yet it would impose a significant, additional administrative burden on member companies.

Medicines Australia acknowledges that the ACCC has a broad discretion to impose conditions on authorisation. However, this discretion is not unfettered. The Australian Competition Tribunal (the **Tribunal**) in *Re Medicines Australia Inc* [2007] ACompT 4 set out the three circumstances in which the ACCC can properly impose a condition.¹ Only the third basis is relevant to the hospitality condition. This basis provides that the ACCC can impose a condition without which it would not be prepared to exercise its discretion in favour of authorisation. The Tribunal went on to say that it is not for the ACCC, or the Tribunal, to use the conditioning power and its discretion to construct and impose its preferred system of self-regulation.² Medicines Australia understands that the ACCC

¹ *Re Medicines Australia Inc* [2007] ACompT 4 at [133].

² *Re Medicines Australia Inc* [2007] ACompT 4 at [134].

might consider a hospitality condition desirable. However, this is no basis for the ACCC to impose such a condition. Indeed, it is inconceivable that in the light of the points raised above, the ACCC would not authorise the Code in the absence of a hospitality condition. Therefore, in Medicines Australia's respectful submission, to impose such a condition is tantamount to redrafting the Code and engaging in regulatory overreach. As the Tribunal warned, in exercising this discretionary power the ACCC (or the Tribunal) should have regard to any burdens the condition may impose upon the party seeking authorisation.³

A further factor directly relevant to the counterfactual, is the view of Medicines Australia's leadership that if a hospitality condition is imposed on Edition 18, it is more likely than not that member companies would reconsider seeking authorisation for Edition 18 and withdraw the authorisation application.

2 Edition 18 of the Code sufficiently regulates the provision of hospitality

Medicines Australia submits that aggregate hospitality reporting is not required in circumstances where Edition 18 of the Code will, in any event:

- capture the majority of interactions with healthcare professionals that include the provision of food and beverages (as outlined in Medicines Australia's submission of 19 December); and
- contain multiple provisions which regulate the provision of hospitality.⁴ In particular, Medicines Australia reiterates that Edition 18 of the Code imposes a mandatory rule which prohibits a member company from spending more than \$120 on a meal (including beverages) provided to a healthcare professional: section 9.4.3.⁵ The mandatory rule ensures that the provision of expensive meals is explicitly prohibited under the Code and provides clarity and certainty for member companies and healthcare professionals.⁶

3 Significant administrative burden in requiring ongoing hospitality reporting

Requiring member companies to continue to report on the hospitality provided to healthcare professionals, even in aggregate form, will impose a significant time and cost burden on member companies.

As outlined in Medicines Australia's submission of 19 December 2014, the current educational event reporting system involves considerable administrative efforts on the part of member companies. Information must be:

- collected, often requiring a compliance officer to review hundreds of invoices and receipts to determine what must be reported;
- manually transcribed into the format required in the educational event reporting template; and
- reviewed for accuracy before publication.

³ *Re Medicines Australia Inc* [2007] ACompT 4 at [133].

⁴ See Code Edition 18 sections 9.3, 9.7.7, 9.5.5 and 9.13.

⁵ This amount is similar to the limit imposed in several European countries which have implemented activity based transparency reporting pursuant to the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (15 August 2013).

⁶ While this mandatory rule is contained in section 9.4 of the Code, which relates to educational events, Medicines Australia directs member companies (and member companies understand) that the \$120 cap applies to *all* meals provided to healthcare professionals, including those that do not involve educational events.

The information required for transparency reporting under Edition 17 is not available 'at the press of a button' and is not readily ascertainable from member companies' existing financial data. Staff must physically review invoices and manually insert information into the relevant templates. This is a time consuming process.

If member companies were required to maintain the current reporting on hospitality, or to report the aggregate amount spent on providing food and beverages to healthcare professionals at educational events, staff would still need to capture data at a transactional level and manually review every invoice generated for a relevant event to determine:

- if the event is 'reportable' under Edition 18 of the Code (ie if it relates to an educational seminar, consultancy, advisory board meeting etc.);
- if hospitality was provided at the event;
- the amount spent on hospitality; and
- the number of attendees for whom hospitality should be reported, that is, the proportion of the expenditure relating to healthcare professionals (as opposed to, for example, expenditure relating to member company staff who were also present at the event).

Member companies do not routinely collect this type of data and would not do so absent the requirements in Edition 17. Although member companies have budgets associated with providing education to healthcare professionals, such budgets generally provide for a single maximum amount to be expended on such activities annually/quarterly, or provide for a maximum amount to be spent on such activities on an event by event basis.

As the ACCC is aware, the new transparency regime in Edition 18 of the Code will require member companies to report on certain transfers of value made to healthcare professionals, by healthcare professional name. To undertake this more complex and detailed reporting, member companies will need to overhaul their existing systems and processes to accommodate individual healthcare professional reporting. This will be a time consuming and costly exercise. The differences in the reporting requirements under Edition 18 will also be such that the same system cannot be used for both reporting under the new regime and for any ongoing aggregate hospitality expenditure report.

Requiring hospitality reporting at an aggregate level would therefore require member companies to maintain two reporting systems – one dealing with hospitality (essentially involving a similar data collection exercise as currently required under Edition 17) and one dealing with the requirements of the new transparency reporting regime. The associated administrative time and costs would be significant. By way of example, staff would not be able to be deployed from working on the current reporting requirements to work on preparing the new transparency reports, rather they would be required to undertake both tasks in parallel. Member companies, many of which have downsized recently, would be required to employ more human and other resources to meet such requirements.

4 Aggregate reporting of hospitality does not provide meaningful information for consumers

The significant administrative burden associated with requiring member companies to operate two reporting regimes should also be considered in the light of the potential benefits associated with providing aggregate hospitality reporting.

Medicines Australia submits that requiring member companies to compile and report on their aggregate hospitality expenditure would provide little, if any, meaningful information to consumers. Such a report would not:

- give any context on the types of educational events held by member companies or the background of the audience. It would therefore not be clear that the hospitality was being provided in association with education;
- provide information on the duration of an educational event or its content;
- provide information on the number of attendees at an event; or
- provide information on the timing of the event and details of the venue.

Providing an aggregate hospitality expenditure figure would also fail to allow the public to extrapolate any trends relating to hospitality expenditure, for example, whether it is increasing or decreasing year on year. This is because annual changes in an aggregate figure would not take into account any growth trends in the industry overall, the growth in size of an individual company or its product portfolio (a member company may have introduced multiple new medicines to the Australian market) or the decline in size of a company (following, for example, patent expiry). Aggregate reporting of hospitality would therefore be of little or no practical benefit.

Moreover, in 2009, when the ACCC authorised Code Edition 16, the Commission stated:

The Code provides, among other things, a standard to address potential conflicts of interest from unrestricted relationships between pharmaceutical companies and healthcare professionals, which may harm consumers, for example through inappropriate prescribing by healthcare professionals.⁷

With respect, and with the benefit of hindsight, it is clear that hospitality reporting in aggregate, could not and would not bring transparency to *relationships* because there would be no reporting of any particular relationships (namely those between an individual healthcare professional and a pharmaceutical company). It follows that the then stated desire to address inappropriate prescribing by healthcare professionals ('which may harm consumers') could not be achieved by aggregated reporting of hospitality. These concerns are now effectively addressed both by the prohibition in Edition 18 (such that relationships could no longer be termed 'unrestricted') and more particularly by reporting at the individual healthcare professional level. These stated aims of the ACCC, which still apply today, will be met by Edition 18.

Medicines Australia member companies have been reporting educational events for more than seven years in an aggregated form, as required by the ACCC. These reports have received little interest and attention from the public and largely go unnoticed these days. Therefore, Medicines Australia submits that there will be limited, if any, realisable benefits in continuing to report educational events.

The ACCC has made clear its view that consumers and other stakeholders now demand more detailed and specific information on payments and transfers of value that have the risk of creating a conflict of interest. It would be a backward step to require aggregated reporting of hospitality when Medicines Australia has responded to consumer and stakeholder expectations of providing specific detailed transparency reporting at the individual healthcare professional level.

Medicines Australia therefore questions strongly the utility of such a condition and submits it would achieve little for the community.

⁷ This appeared in the ACCC Media Release titled 'Transparency is the key for drug industry relationships' (see <http://www.accc.gov.au/media-release/transparency-is-key-for-drug-industry-relationships-0>).

5 A hospitality condition would not be an appropriate exercise of the ACCC's discretion

As mentioned above, the Tribunal recognised in *Re Medicines Australia* that the ACCC does not have '...an unconfined discretion to impose whatever conditions the ACCC... considers appropriate'. Instead, the Tribunal recognised that the ACCC is 'constrained... by the subject matter, scope and purpose of the statute'.⁸

The Tribunal set out three reasons for the imposition of a condition on authorisation, as follows:⁹

1. Where there is no or insufficient public benefit in the proposed conduct, a condition may be imposed requiring a variation of the proposal to yield the requisite public benefit.
2. Where a theoretically sufficient public benefit has been identified, a condition may be imposed to vary the proposal so that the likelihood of the benefit resulting is raised to a sufficient level.
3. Where the proposal has satisfied the relevant public benefits test, a condition may be imposed without which the ACCC would not be prepared to exercise its discretion in favour of authorisation. The range of permissible conditions under this head is limited by the range of considerations relevant to the exercise of the discretion. The Tribunal also considered it appropriate for the ACCC to have regard to any burdens it may impose upon the party seeking authorisation.

Unlike the scenario considered by the Tribunal in *Re Medicines Australia*,¹⁰ the imposition of a condition requiring aggregate reporting of hospitality could not enhance compliance with and enforcement of the Code. This is because Edition 18 now sufficiently regulates the provision of hospitality and, in any event, aggregate reporting would provide little, if any, meaningful information or practical benefit to consumers. Further, the significant administrative burden and costs associated with requiring member companies to operate two reporting regimes is unreasonable and considerably outweighs the minimal, if any, resulting public benefit.

In its draft determination dated October 2014 the ACCC, in considering the possible imposition of a proposed condition on hospitality, observed that 'there is merit in including some form of continued reporting of hospitality provided by member companies'.¹¹ Medicines Australia considers the question is not whether the proposed condition is desirable, but whether without the condition the ACCC, in exercising its discretion, would not be willing to authorise the Code. In Medicines Australia's respectful submission, it is inconceivable that the ACCC would form the view that without the condition it will not authorise Edition 18 of the Code, given the substantial additional public benefit including the move to reporting of information at an individual healthcare professional level.

As a result, Medicines Australia considers that the imposition of a condition requiring aggregate reporting of hospitality goes beyond that envisaged by the Tribunal in *Re Medicines Australia* when it set out the circumstances in which imposing a condition on authorisation is permissible. It is not for the ACCC to use the conditioning power and its discretion, to construct and impose its preferred system of self-regulation.

⁸ *Re Medicines Australia Inc* [2007] ACompT 4 at [129].

⁹ *Re Medicines Australia Inc* [2007] ACompT 4 at [133].

¹⁰ *Re Medicines Australia Inc* [2007] ACompT 4 at [363].

¹¹ ACCC, *Draft Determination, Applications for revocation and substitution of authorisation lodged by Medicines Australia Limited in respect of the Medicines Australia Code of Conduct edition 18*, 17 October 2014, paragraph 322 (available at <http://registers.accc.gov.au/content/trimFile.phtml?trimFileTitle=D14+141443.pdf&trimFileFromVersionId=1184134&trimFileName=D14+141443.pdf>).

6 What this means for Medicines Australia

As the ACCC is aware, no other pharmaceutical industry body has implemented and/or sought authorisation for a code of conduct as detailed and prescriptive as the Medicines Australia Code. Although the GMiA introduced a code of conduct in March 2010, that code is no longer authorised by the ACCC and GMiA has not sought authorisation for the most recent edition of its code. Members of Medicines Australia are therefore in a decidedly different position from their generic competitors (and medical device manufacturers) who are subject to considerably less constraint in their dealings with healthcare professionals. There is no level playing field in the therapeutic products industry.

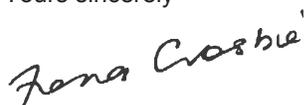
Medicines Australia is of the view that it is inappropriate to impose a condition on hospitality reporting, that would significantly increase the burden on its member companies (to no discernible benefit) while the regulation of its competitors is decreasing. Although Medicines Australia is proud to have introduced a new version of the Code that provides a considerable qualitative difference to the existing transparency reporting, it considers that the imposition of a hospitality reporting condition will further exacerbate the inequity between the treatment of its members versus their competitors.

Medicines Australia's leadership therefore considers that:

- If a hospitality condition is imposed by the ACCC, it is more likely than not that member companies of Medicines Australia would reconsider seeking authorisation for Edition 18 of the Code and withdraw the authorisation application. As a result, the public benefits associated with Edition 18 of the Code and its new transparency reporting regime would be lost. This is a relevant factor that should be taken into account when the ACCC assesses the relevant counterfactual.
- It would be difficult for Medicines Australia to attract new members to the industry body as many pharmaceutical companies would simply find the dual reporting requirements too onerous.

We would be pleased to discuss and/or meet with the ACCC about these matters.

Yours sincerely



Fiona Crosbie
Partner
Allens
Fiona.Crosbie@allens.com.au
T +61 2 9230 4383

Catherine Bembrick
Senior Associate
Allens
Catherine.Bembrick@allens.com.au
T +61 2 9230 5167