

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

19 December 2014

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

In this letter Medicines Australia provides a supplementary submission in respect of:

- continued hospitality reporting in Edition 18 of the Medicines Australia Code of Conduct (the **Code**); and
- the establishment of a centralised database.

1 Transparency reporting in Edition 18 of the Code is more meaningful for consumers

As outlined in Medicines Australia's submission of 21 November 2014, Medicines Australia strongly submits that a condition on authorisation which requires continued reporting on the hospitality provided by member companies to healthcare professionals is not necessary.

Over the years Medicines Australia has consistently sought to develop the Code to ensure that it continues to meet industry and community expectations. In authorising Edition 15 of the Code, the Australian Competition Tribunal imposed a condition requiring member companies to report on hospitality provided at all educational meetings held or sponsored by them, and since 2007 Medicines Australia has completed 15 'rounds' of six-monthly educational event reporting.

The scope of these educational event reports has expanded in successive versions of the Code. In Edition 16 Medicines Australia required member companies to report on the provision of financial support to Health Consumer Organisations. In Edition 17 Medicines Australia required member companies to also provide detailed information on the sponsorship of healthcare professionals to attend educational meetings held by third parties, to speak at educational meetings and required separate reports on payments made to healthcare professionals to act on advisory boards or provide other consulting services.

The changes proposed in Edition 18 of the Code reflect the growing community expectation that transfers of value to healthcare professionals must be disclosed, with a focus on those interactions where there is a higher perceived risk of influence. Edition 18 of the Code therefore requires member companies to report, **by healthcare professional name** any:

Our Ref FVCS:CHBS:206029656

chbs A0131578347v5 206029656 18.11.2014

Allens is an independent partnership operating in alliance with Linklaters LLP.

- sponsorship to attend educational events including travel, accommodation and registration fees;
- fees for speaking at an educational event;
- fees paid to healthcare professional consultants – in 2013 there were approximately 728 consultancies provided to member companies, involving over 1000 healthcare professional consultants;
- fees paid to advisory board members for relevant work – there are approximately 200 advisory board meetings held each year with around 1500 healthcare professional attendances;¹ and
- fees paid for market research (where the individual healthcare professional is known).

The new regime is similar to the activity based model adopted by the EFPIA in Europe. The regime captures and highlights those transfers of value which are significant, while avoiding 'low level noise' which will be, in any event, subject to a number of other provisions in the Code which regulate the provision of hospitality.²

Where only hospitality (food and beverages) is provided to a healthcare professional, a member company will not be required to report this information at an individual healthcare professional level or in aggregate. However as the ACCC is aware, Edition 18 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 9.4.3.³ 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.

Medicines Australia considers that the amendments in Edition 18 represent transformational change for the industry. The new reporting requirement is qualitatively different and more meaningful for consumers. The new reporting regime does not simply involve a 'swap' from the existing educational event reporting requirements (which reflect the thinking of seven years ago), it delivers the fundamental purpose of transparency and provides specific and detailed information at the individual level. The new regime therefore provides the more targeted approach requested by consumers.

2 Significant administrative burden in reporting

The current educational event reporting system involves considerable administrative effort and cost on the part of member companies. Information is not simply available at the 'press of button'. Information must be collected, often requiring a compliance officer to review relevant invoices and receipts to determine what is required to be reported. An individual must then transcribe the relevant information into the format required in the educational event reporting template for each event – resulting in multiple lines of data that must then be checked for accuracy before ultimately being provided to Medicines Australia for publication.

Member companies have employed compliance staff to complete this work, and the workload of such staff has increased as the scope of reporting has also expanded from Edition 15 to Edition 17. Medicines Australia staff are also involved in this process, with two staff members reviewing the

¹ There may be some overlap as a healthcare professional may attend more than one advisory board meeting in a year.

² See sections 9.3, 9.7.7, 9.5.5 and 9.13.

³ 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).

educational event reports provided by companies to ensure that they are complete and that there are no obvious errors in the data before publication.

The new reporting regime under Edition 18 will require additional effort on the part of staff at member companies as there is greater detail and complexity involved in producing reports by individual healthcare professional name. The process will likely involve:

- record keeping associated with ensuring that informed consent for publication has been obtained or a collection notice provided to the healthcare professional;
- ensuring that a healthcare professional's details are managed appropriately, including ensuring that information is accurate and that expenditure is attributed to the correct healthcare professional; and
- additional lines of data will need to be reviewed, as the reporting will be done by individual not in the aggregate.

To complete these tasks member companies need to be able to redeploy staff currently involved in creating the aggregate educational event reports so that they can concentrate their efforts on the new regime.

If the ACCC were to require Medicines Australia's member companies to continue providing hospitality reporting in the aggregate, as well as reporting by name under the new transparency regime, this would create large administrative and compliance burdens for members and associated costs. Such a burden is not necessary in circumstances where the new transparency regime will provide significant transparency of key interactions and is qualitatively superior to, and different from, the old regime.

As the ACCC is aware, no other industry association or healthcare professional organisation has offered to assist with this reporting and therefore the burden will fall entirely to the members of Medicines Australia.

3 The new transparency reporting regime will capture key data

The new transparency reporting regime in 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.

Based on a review of data in the current educational event reports, Medicines Australia estimates that approximately 68% of the current amount provided by member companies to healthcare professionals will be reported under Edition 18. The key point to note is that, unlike the current regime, reporting will now be done at the **individual healthcare professional level** or, for reporting of sponsorship provided to third party entities, by the name of the third party recipient. There is therefore, as discussed above, a **qualitative difference** in the nature of the reporting.

The largest expenditure incurred by member companies in their interactions with healthcare professionals is sponsorship to attend an educational meeting such as a conference. In Edition 18, Medicines Australia estimates that approximately 96% of expenditure associated with such events will now be recorded at individual healthcare professional level.

Similarly, Medicines Australia estimates that approximately 98% of the costs associated with consulting services and 84% of the costs associated with advisory boards will be reported at the individual healthcare professional level. The costs that will not be reported are those associated with the provision of food and beverages, room/AV hire and transfer costs. This expenditure will remain subject to other provisions in the Code that regulate member company behaviour such as the \$120 mandatory cap for expenditure on food and beverages.

For sponsorship of third party run educational events (such as a grand round organised by a hospital), any transfer of money to that third party will be reportable by the name of that third party. Expenditure associated with bringing in a plate of food (such as sandwiches to a lunch time meeting) would not be recorded. Medicines Australia estimates that at least 71% of the total function costs for these events (incurred by member companies) will be reportable under Edition 18, by the name of the recipient entity. In any event, the educational content of these meetings is not determined by member companies.

For company organised educational events where only food and beverages are provided to healthcare professionals, which comprise around 40% of events, these interactions would not be reported under Edition 18. However, Medicines Australia estimates that the food and beverages provided at such events represent only 13% of the total expenditure of member companies on functions in a given month. Of course, if educational content at a company meeting is provided by a healthcare professional who is paid a speaking fee, the speaking fee is reportable (by name) as are the travel and accommodation costs of speakers or attendees.

The bulk of expenditure will be captured in the new reports as follows:⁴

Transfer of value	Reportable?
Speaking fees	Yes – by individual healthcare professional name
Advisory board services	Yes – by individual healthcare professional name
Consultancy fees	Yes – by individual healthcare professional name
Sponsorship to attend educational meeting including travel, accommodation and registration fees	Yes – by individual healthcare professional name. If a conference dinner were provided (and sponsored) this would not be reportable but the mandatory limit of \$120 would apply
Sponsorship of third party event	Yes – for monetary transfers of value, reportable by recipient entity name No – if member company brings in plate of food to a meeting, or pays the venue directly
Support to Health Consumer Organisation	Yes – by HCO name
Educational events run by member companies	Yes – if speaking fee paid to a healthcare professional or travel and accommodation costs provided to attendees, by healthcare professional name No – if only hospitality (food and beverages) is provided at the event, noting that (a) such activity only comprises around 13% of expenditure on functions by members, (b) mandatory limit of \$120 will apply, and (c) other Code provisions apply to regulate expenditure

Medicines Australia therefore submits that in circumstances where:

- the administrative burden associated with preparing two sets of reports is significant;

⁴ Noting that AV hire, room hire, parking and transfer costs are not reportable under Edition 18.

- the new transparency regime in Edition 18 is designed to (and will) capture meaningful transfers of value and report those transfers by individual healthcare professional name – thereby meeting community expectations; and
- where the majority of interactions involving hospitality will still be reported under Edition 18 of the Code,

a condition requiring ongoing hospitality reporting, either by name or in aggregate, should not be imposed by the ACCC.

4 Centralised database

There are a number of practical issues that must be considered and addressed before Medicines Australia and its member companies can fully commit to or implement a centralised database for transparency reporting. In addition to the general issues identified in the 21 November 2014 submission, the following will need to be considered:

- **Privacy requirements:** the key tasks and issues to consider when setting up a centralised database would include:
 - conducting a Privacy Impact Assessment in accordance with the Privacy Commissioner's recommendation, in circumstances where the storage of personal information in a centralised database poses potential privacy risks; and
 - ensuring that member companies (and Medicines Australia) can comply with privacy legislation, both when obtaining personal data and when transferring that data to an external database (or to a third party provider managing that database).
- **Technical issues associated with establishing a database:** these would include:
 - how to process the large volume of data required under the new transparency regime in Edition 18, which may extend to thousands of individual lines of data;
 - how to ensure that data is collected/retained in the most appropriate format for inclusion in a database; and
 - ensuring member companies' CRM systems are compatible with any external system adopted so that data can be transferred between systems.
- **Accuracy:** it will be necessary to consider how member companies (and Medicines Australia) can best ensure that any data collected is accurate and attributed to the correct healthcare professional (both initially and when data is transferred out of a member company's internal systems). In this regard, a unique identifier for each healthcare professional will need to be set up and developed in circumstances where it will not be possible to use AHPRA numbers.
- **Funding the database:** Medicines Australia and member companies will need to consider how the database would be funded, in circumstances where establishing a database is likely to be costly and where ongoing funding would be required to manage the database. Medicines Australia Board approval would be required for any such decisions.

Medicines Australia does not consider that these issues are insurmountable. As outlined in the 21 November 2014 submission, Medicines Australia will liaise with its member companies to discuss the development of a centralised database and will establish a working group to consider and progress these issues. In relation to this working group, Medicines Australia will:

- invite representatives from its member companies' CFO and legal teams to join the group in order to consider any internal processes and legal requirements that member companies consider would be involved in establishing a database;
- identify appropriate technical and IT specialists to join the group to advise on technical issues associated with establishing a database; and
- require the group to prepare a report for Medicines Australia's Board on the outcome of the working group's assessment of the issues above. The report would be due to the Board between June and September 2015. The Board will then formulate a recommendation for member companies to consider.

Medicines Australia will also liaise with its member companies in the first six months of 2015 to ensure that when member companies begin collecting the individual healthcare professional data required under Edition 18, it is collected in a uniform fashion and in an appropriate format to allow the data to potentially be included in a centralised database in the future.

Overall, Medicines Australia considers that a period of at least two to three years would be required in order to (a) investigate and potentially establish a centralised database that fulfils the requirements of Medicines Australia, member companies and stakeholders and (b) avoid the implementation issues that have been experienced in other jurisdictions – such as in the US pursuant to the Physician Payments (Sunshine) Act.

Medicines Australia looks forward to continuing to work with the ACCC on these issues in 2015.

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