

**SUBMISSION ON THE REVIEW OF THE MEDICINES AUSTRALIA****CODE OF CONDUCT EDITION 17****ALLERGAN AUSTRALIA PTY LTD**

Allergan Australia Pty Ltd makes the following comments with regard to the review of the current Medicines Australia Code of Conduct Edition 17:

1. General Comments

- a. Allergan is committed to the patients who benefit from our products and the healthcare professionals who trust our products. Our interactions with healthcare professionals play an important role in enhancing medical knowledge, and we acknowledge that patients and the community in general increasingly desire openness on these interactions.
- b. We support and acknowledge moves toward greater controls on industry interactions with healthcare professionals, along with increased transparency. As such, we welcome transparency initiatives provided they are established to support a level playing field across all pharmaceutical and device companies and all therapeutic goods. However currently this is not the case in Australia in that only Medicines Australia members would be required to report, at considerable cost and resource requirements.

2. Specific Comments on Transparency Model – Consultation and Discussion Paper

a. Section 1 General Requirement

Allergan collates information for the current Code reporting requirements manually. Although the company is working to make this process more automated, resources available locally are limited and implementing systems to capture data by January 2015 will be extremely difficult and costly. Further, until such time as the ACCC authorises Edition 18 of the Code members will not have certainty as to the scope of reporting. The scope of reporting will factor into systems requirements and may likely extend possible implementation beyond January 2015.

The Transparency Model proposed disclosure of payments made in the calendar year 2015 by June 2016. Allergan suggest timing of this be delayed and be based on the financial year i.e. disclosure of payments July 2015 – June 2016 by Dec 2016. This suggestion would allow (i) an additional 6-9 months from ACCC authorisation for member companies to implement reporting systems, and (ii) the bulk of collation and review of the report would not occur during the Christmas holiday period.

b. Section 3.7 Category of payment or transfer of value

Allergan suggests the category Honorarium may be more appropriately named Advisory Board. Honorarium is often used, whether correct or not, in relation to payment for speakers and consultants and renaming this category may avoid confusion.

c. Section 3.8 Payment to third parties, including registered charities

Allergan interprets this section to cover situations where the payment for services provided by a healthcare professional made to a related business, hospital or other healthcare organisation, must be reported. This is not explicitly stated and clearer guidance may be required.

d. Section 4 Requirements for payments or other transfers of value related to continuing professional development (CPD) programs

The Transparency Model excludes, if conditions are met, the reporting of CPD programs. This would seem to be contrary to increased transparency called for by the community in general.

However given: (i) Section 37.4 of the current Code requires member companies to report all sponsored educational meetings and symposia, such as CPD programs, and (ii) it is often difficult to establish individual healthcare professionals who are recipients of the transfer of value related to CPD programs and other sponsorship of third party educational events; it would seem reasonable to exclude payments or other transfers of value related to CPD programs from Transparency Model reporting requirements for individual healthcare professionals, provided it is maintained in the Educational Event report.

See comment below regarding suggested changes to the Educational Event Report under 3c.

e. Section 5.2 Reporting threshold

As mentioned in 2a. General Requirements, Allergan collates information for the current Code reporting requirements manually. We share concerns expressed by other members on the complexity of capturing low level hospitality provided by sales representatives. Allergan sees no value in reporting these large volume, low cost transactions and would argue that they may dilute the intention of and principles for transparency.

Allergan suggest a recording threshold of \$50, with reporting for individual healthcare professionals when aggregate payments exceed \$1,000 in a financial year.

Non-hospitality and non-travel function costs should not be allocated as a transfer of value to the healthcare professionals who have attended an educational meeting. Educational Event Reports have been required since 2007, therefore unless Medicines Australia has evidence of 'cost shifting' of food and beverage costs to non-reportable function costs, concerns expressed by Transparency Working Group members are unwarranted.

f. Section 5.3 Clinical Research

The Transparency Model has not provided reasons why payment for clinical research has been excluded from reporting, whereas for example, royalty or licence fee payments are included. Member companies, as well as community groups and other stakeholders may benefit from the reasoning behind this exclusion.

g. Section 6 Procedures for electronic submission of reports

As discussed in 2a, Allergan suggest reports are based on the financial year, with the first report electronically submitted by November 2016. The report would then be published by December 2016 for the preceding financial year (1 July – 30 June).

Allergan believes electronic submission of reports to Medicines Australia is, at present, the most appropriate option. While a level playing field, with all therapeutic goods sponsors required to report payments and other transfers of value to healthcare professionals is the ultimate aim, in reality without consensus from industry associations or government intervention this may be a number of years away.

Allergan suggest Medicines Australia invests in database capacity or a platform that is easily transportable to a third party, should the need arise in the future.

h. Section 6.3 General rules

The transparency model refers to joint ventures and reporting requirements related to these. However Allergan suggests more clarity is needed around reporting requirements with distribution or co-promotion agreements between two or more companies. In particular, where such an agreement involves a MA member company and a non MA member company is there an obligation to report payments to healthcare professionals.

i. Section 7 Period for review and error correction

Allergan suggests Medicines Australia, if not already done, seek legal advice in relation to the data review and dispute process. Publication of individual healthcare professional data and Privacy Act requirements will have implication for member companies.

Allergan agrees that healthcare professionals must have the opportunity to review and submit corrections for payments assigned to them. However a single 45 day period to review 12 months of data may be insufficient time particularly for healthcare professionals who interact with several member companies. We suggest that healthcare professionals be provided data for review at 6 monthly intervals in March and September.

In circumstances where a payment is disputed and not resolved prior to the publication date, it may not be fair or appropriate to attribute payment to a named healthcare professional. Allergan suggests initially it may be more appropriate to identify the payment by 'name withheld – under dispute'. Once the dispute is resolved the published data should be updated with the healthcare professional's name. However it may be prudent to set dispute resolution timelines so that it is not unnecessarily protracted and publication delayed indefinitely.

3. Specific Comments on Individual Code Sections

- a. For Code sections not specifically discussed below, Allergan supports maintaining the Code sections as is.
- b. Section 9.10 Reporting payments to healthcare professional consultants and advisory boards

The Transparency Model proposes more detailed reporting of payments and other transfers of value to consultants and advisory board members. If these proposals are adopted, the current Section 9.10 should be deleted.

- c. Section 37.4 Educational event reports

This section should be reviewed in light of the proposed Transparency Model. As payments for hospitality, travel, accommodation, registration etc will be attributed to individual healthcare professionals, the educational event report should only require those events where individual healthcare professionals who benefit from sponsorship cannot be easily identified. Examples of these types of sponsorship would include CPD programs (the type excluded from the transparency model mentioned in Section 2d), third party conferences and congresses.