

New Australian pharmaceutical code increases reporting - with more to come

On 20 December 2012, the Australian Competition and Consumer Commission (ACCC) authorised edition 17 of Medicines Australia's Code of Conduct (MACC) for two years only. Medicines Australia had sought authorisation for five years.

The MACC is a voluntary code of conduct that regulates interactions between Medicines Australia's pharmaceutical member companies and healthcare professionals, such as pharmacists and doctors. All member companies must adhere to the MACC.

Membership of Medicines Australia is voluntary, but its member companies supply 86% of the medicines that are available to Australian patients through the Pharmaceutical Benefits Scheme.

One of the new requirements introduced by edition 17 of the MACC is that member companies must provide Medicines Australia with aggregate details of the fees they have paid to healthcare professionals in Australia, or to their employers on their behalf, for:

- educational events
- preparation of promotional materials or product position papers
- chairing and speaking at educational meetings
- assistance with training and participation on advisory boards
- other therapy advice.

Disclosure is also required of all payments made to healthcare professionals for hospitality, accommodation and any travel undertaken, both within and outside Australia. Medicines Australia will publish these details on its public website.

This move is consistent with increasingly stringent spend data reporting requirements in other jurisdictions, most notably in the United States.

In summary, member companies will now be required to report to Medicines Australia:

Key issues

- The ACCC authorised edition 17 of MACC for two years only, until 11 January 2015
 - Member companies will now have more extensive reporting obligations to Medicines Australia, including in relation to the amount of fees and benefits they provide to healthcare professionals in Australia
 - The ACCC has asked Medicines Australia to address the issue of individual disclosure and develop a process for reporting individual payments so that public reporting can begin in early 2015.
- all consultancy fees paid to healthcare professional consultants, including total costs of any hospitality, accommodation (both within and outside Australia) and travel, paid on or after 1 January 2013. An initial report for the 2013 calendar year must be submitted by 30 April 2014 and annually thereafter
 - sitting fees, costs of any hospitality, accommodation (both within and outside Australia) and travel, venue and other third-party costs associated with advisory boards held on or after 1 January 2013. An initial report

Medicines Australia

Medicines Australia is a voluntary member-organisation, comprising firms or companies operating a prescription pharmaceutical or other medicines or vaccines business in Australia and includes both research and non-research based companies.

covering the period 1 January 2013 to 31 March 2013 must be submitted by 30 April 2013 and at six-month intervals thereafter

- details of the health consumer organisations to which it provides direct financial support and/or significant direct or indirect non-financial support, the monetary value of the financial support, and a description of significant non-financial support that cannot be assigned a meaningful monetary value. The first report is to be submitted by 30 April 2014 to cover activities in the year starting from 1 January 2013 and annually thereafter
- details of sponsorships of healthcare professionals or non-healthcare professionals to attend any educational event held on or after 1 January 2013 as well as payments made to speakers to attend and give a

presentation at an educational event. Details are to include registration fees, costs of accommodation (both within and outside Australia), travel and any honorariums. The first report for the period 1 January 2013 to 31 March 2013 must be submitted by 30 April 2013.

Whilst the ACCC has acknowledged that the MACC provides the public with greater transparency around the relationships between pharmaceutical companies and healthcare professionals, it has also expressed the view that Medicines Australia could go further in ensuring the MACC met the public's increasing expectations of disclosure by the pharmaceutical industry. The ACCC specifically referred to the disclosure of payments made to individual healthcare professionals.

The ACCC considers that a two-year period of authorisation is a feasible amount of time for Medicines Australia to address the issue of individual disclosure and develop a process for reporting individual payments such that public reporting will be able to begin early 2015. The ACCC has made clear that Medicines Australia's response will be critical to future authorisation of new editions of the Code.

Edition 17 of the MACC came into

effect on 1 January 2013. Accordingly member companies will need to ensure that they have policies and processes in place to record and report the necessary data so that they can comply with the MACC.

Authorisation of the MACC provides statutory protection from court action for conduct which would otherwise give rise to concerns under the competition provisions of the Competition and Consumer Act 2010 where it meets the net public benefit test.

Contacts**Peter Dieners**

Partner

T: +49 211 43 555 468

E: peter.dieners@cliffordchance.com

Diana Chang

Partner

T: +61 2 8922 8003

E: diana.chang@cliffordchance.com

Dave Poddar

Partner

T: +61 2 8922 8033

E: dave.poddar@cliffordchance.com

Jerrem Ng

Senior Associate

T: +61 2 8922 8069

E: jerrem.ng@cliffordchance.com

This publication does not necessarily deal with every important topic or cover every aspect of the topics with which it deals. It is not designed to provide legal or other advice.

Clifford Chance, Level 7, 190 St Georges Terrace, Perth, WA 6000, Australia
Clifford Chance, Level 16, No.1 O'Connell Street, Sydney, NSW 2000, Australia

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