

ACCC delays approval of Australian pharmaceutical code of conduct in search of greater industry transparency

The Australian Competition and Consumer Commission (ACCC) has delayed the introduction of a new edition of a code of conduct for the pharmaceutical industry, expecting further amendments to provide greater transparency to industry sponsorship activities.

That transparency is likely to include mandatory reporting of payments to individual healthcare professionals, rather than the current aggregate reporting by pharmaceutical companies.

Until a new code is approved, the ACCC has temporarily extended the current edition of the Medicines Australia Code of Conduct (MACC).

Introduction

Edition 17 of MACC requires member companies to provide Medicines Australia with aggregate details of fees they have paid to healthcare professionals in Australia or to their employers on their behalf for various events (such as educational events) and engagements.

Under edition 17, disclosure is also required for all payments made to healthcare professionals for hospitality, accommodation and any

travel undertaken both within and outside Australia.

When it authorised edition 17 of the MACC in 2012 for two years until 11 January 2015 (rather than the five years sought by Medicines Australia), the ACCC requested that Medicines Australia introduce greater transparency and disclosure provisions to the reporting of payments and benefits provided by member companies to individual healthcare professionals (eg for sponsorship fees, speaker fees,

Key issues

- The MACC is a voluntary industry code of conduct that regulates the behaviour of Medicines Australia's member companies.
- Medicines Australia's member companies supply 86% of the medicines available under the Pharmaceutical Benefits Scheme.
- Under the current code, pharmaceutical companies provide aggregate details of fees they have paid to healthcare professionals in Australia for educational events, engagements, hospitality, accommodation and any travel undertaken both within and outside Australia.
- In the latest revision of the code, Medicines Australia proposed a move to individual reporting of such payments – but only where the healthcare professional consented to such disclosure.
- ACCC has suggested a regime where payments are not made *unless* the healthcare professional agrees to disclosure.

consultation fees and advisory board member fees) in the next edition of the MACC.

Proposed edition 18 of MACC

In July 2014, Medicines Australia applied to the ACCC for authorisation of edition 18 of the MACC.

Whilst edition 18 makes a number of amendments to edition 17, one of the most significant amendments proposed to address transparency concerns is the requirement to report payments or transfers of value to healthcare professionals on an individual basis.

The ACCC received a number of submissions on these aspects and provided a draft determination on edition 18 on 17 October 2014.

Individual reporting

In its initial application for ACCC authorisation of edition 18, Medicines Australia responded to the ACCC's request for greater transparency around payments or transfers of value by proposing transitioning from reporting in an aggregate manner to reporting on an individual basis.

Medicines Australia proposed that from 1 October 2015 member companies would be required to report to Medicines Australia the amount of payment or transfer of value of the following, for each individual healthcare professional, by their name:

- consulting fees and/or speaking fees;
- sponsorship of a healthcare professional to attend educational events including airfares, accommodation and/or registration fees (whether held within or outside Australia);

- fees paid to healthcare professional consultants in Australia, or to their employers on their behalf, for specific services rendered by them including consulting fees, accommodation and airfares (whether within or outside Australia), preparation of promotional material;
- sitting fees, accommodation and airfares (whether within or outside Australia) paid to healthcare professionals in their role as Advisory Board members;
- fees paid for the purpose of market research but only where the identity of the healthcare professional is known to the company; and
- payment of an educational grant or sponsorship to a specific healthcare professional.

Where the healthcare professional requests that any of these listed transfers of value be paid to a third party, the payments must still be reported for that individual healthcare professional.

Content of reports

Medicines Australia also proposed in its initial application for authorisation of edition 18 that all reports for individual transfers of value to each healthcare professional would include:

- the date of the event or provision of service;
- the healthcare professional's name;
- the type of healthcare professional;
- the healthcare professional's principal practice address;

Timeline

- **December 2012:** ACCC authorises edition 17 of the Medicines Australia Code of Conduct (MACC), stating that it expects Medicines Australia to amend the next edition of the Code to ensure greater disclosure of sponsorship and fees paid to individual doctors.
 - **July 2014:** Medicines Australia seeks authorisation of edition 18 of the MACC which requires member companies to report payments and transfers of values to healthcare professionals on an individual basis, with some exceptions.
 - **October 2014:** The ACCC releases its proposed amendments to edition 18 and extends the deadline for further submissions and feedback from MA and interested parties to 21 November 2014, at the request of MA.
 - **December 2014:** The ACCC extends the operation of edition 17 of MACC until the ACCC's final determination on edition 18 comes into effect. The ACCC's final determination is expected to be made in the first quarter of 2015.
- the description of the service provided (ie. Advisory Board member);
 - the description of the event;
 - whether the payment was made to the healthcare professional or a third party; and
 - the amount of the payment, subdivided into (where relevant) registration fees, travel and

accommodation, and fees for service.

However, individual healthcare professional reporting data would only need to be provided by companies if the healthcare professional consented to their details being disclosed due to the risk of breaching Australian privacy law.

Accordingly, any healthcare professional that withheld consent would have their transfers of value reported in aggregate.

The ACCC's draft determination

In its draft determination on MACC edition 18, the ACCC was not receptive of the proposed consent provisions and noted the various submissions received from various interested parties who were of the view that greater transparency could be provided.

Submissions by interested parties raised concerns about 'opt-in' reporting, submitting that if consent from healthcare professionals was optional, transparency would not be enhanced and this would undermine the purpose of the transparency regime.

The ACCC stated that in order for the proposed individual transparency regime to be effective all transfers of value had to be reported.

It noted that mandatory disclosure would address the principal agent problem by giving consumers insight on matters that may influence the objective and treatment provided by their prescribing healthcare professional.

Individual reporting would also deter member companies from making, and healthcare professionals from

accepting, transfers of value that were inappropriate or which could raise conflicts of interest, as these transfers would be subject to public scrutiny.

Medicines Australia had submitted that reporting all transfers of value could adversely affect the competitiveness of member companies because unlike non-member companies, member companies would not be able to deal with individuals who did not give consent.

While the ACCC acknowledged this concern, it noted that a requirement for all transfers of value be reported would ensure a 'level playing field' between healthcare practitioners in their dealings with member companies.

In its draft determination, the ACCC proposed that it would authorise edition 18 if it was amended to prevent member companies making a transfer of value to a healthcare professional if it had not obtained the healthcare professional's consent to disclose or otherwise comply with the privacy law. This would allow member companies to report all transfers made.

The requirement to have the details of transfers of value for healthcare professionals published, on an individual basis, is consistent with reporting standards in other jurisdictions, in particular the United States (Sunshine Act) and Europe (European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code).

Food and beverage limits remain in question

Medicines Australia also proposed in its initial version of edition 18 to

impose a maximum monetary limit on meals and beverages provided to healthcare professionals, and dispensed with the edition 17 requirement to report expenditure of this kind.

Specifically, it proposed that a member company could not spend more than A\$120 per meal (including beverages) on each healthcare professional (exclusive of GST) and any amount spent in excess of this defined limit would be a breach of the MACC.

The ACCC noted submissions from interested parties who were of the view that the A\$120 limit was too high or that some form of hospitality reporting should be maintained.

In its draft determination, the ACCC stated that there was merit in requiring some form of continued reporting of hospitality transfers of value but also raised alternatives which included a reduction in the A\$120 limit to a level that may be of less concern to the community (eg A\$70).

The ACCC invited further submissions from Medicines Australia and interested parties about whether such conditions would be necessary and the form that it should take.

Other standards for the relationship between companies and healthcare professionals

Medicines Australia also proposed in edition 18 of the MACC the following restrictions on the transfer of value between companies and healthcare professionals:

- travel could only be provided in direct association with educational events and by the

most practical direct route to and from the educational events. The length of stay could not be for more than is reasonably justified to enable effective participation in the educational event;

- financial sponsorship of an independent educational event must be paid to the organisation arranging the event and not an individual healthcare professional;
- amounts paid to an educational meeting organiser for a trade display must be reported.

Current status of edition 18 MACC

In light of various submissions received by Medicines Australia and interested parties on the ACCC's proposed amendments to edition 18 of the MACC, the ACCC has yet to make a final determination to authorise edition 18.

On 4 December 2014, the ACCC granted interim authorisation, which commenced on 10 January 2015, of the MACC for edition 17 (which was due to expire on 11 January 2015) while it is finalising its consideration of edition 18.

The interim authorisation of edition 17 will remain in place until it is revoked or until the date of the ACCC's final determination on edition 18, which is expected to be made in the first quarter of 2015.

Conclusion

The interaction between pharmaceutical companies and healthcare professionals remains a matter of high priority for the ACCC.

It appears that the new reporting regime proposed by the draft edition 18 of the MACC does not meet the level of transparency sought by the ACCC when it granted authorisation to edition 17, nor does it reflect the continued public expectations of transparency in transfers of value in the medical profession.

Public expectations are highlighted by various recent investigations which have occurred in other parts of the world concerning bribery and corruption in the healthcare sector, and the focus by many regulators in targeting unlawful conduct by pharmaceutical companies and healthcare professionals.

Authorisation of the MACC provides statutory protection from court action for conduct that might otherwise raise concerns under the competition provisions of the *Competition and Consumer Act 2010* (CCA) where it meets the net public benefit test.

The ACCC may grant authorisation when it is satisfied that there is a net public benefit.

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