



**Australian
Competition &
Consumer
Commission**

Our Ref: 55039
Contact Officer: Tess Macrae
Darrell Channing
Contact Number: (03) 9290 1835
(02) 6243 4925

GPO Box 3131
Canberra ACT 2601
23 Marcus Clarke Street
Canberra ACT 2601
tel: (02) 6243 1111
fax: (02) 6243 1199
www.accc.gov.au

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Sent via email

Dear Sir/Madam,

**Medicines Australia Limited application for revocation of authorisations
A91316-A91320 and substitution of new authorisations A91436-A91440 –
proposed conditions of authorisation**

The Australian Competition and Consumer Commission (ACCC) is seeking comments regarding the conditions of authorisation it proposes to impose on any authorisation of edition 18 of Medicines Australia Limited's (Medicines Australia) Code of Conduct (the Code).

Background

On 2 July 2014 Medicines Australia sought authorisation for edition 18 of its Code, which is a voluntary industry code of conduct for the prescription medicines industry in Australia.

On 17 October 2014 the ACCC released a draft determination proposing to grant conditional authorisation to the Code for five years.

In edition 18 of the Code, Medicines Australia has proposed a new reporting regime which requires reporting of 'transfers of value' made by its members to individual healthcare professionals, subject to the healthcare professional's consent.

In its draft determination, the ACCC proposed a condition to ensure that **all** relevant transfers of value (as defined in 41.3.1 of the Code) by member companies to individual healthcare professionals are reported. The ACCC also indicated it was considering requiring ongoing hospitality reporting.

Following the draft determination, the ACCC sought submissions from interested parties. A pre-decision conference was also convened at the request of the Royal Australian College of General Practitioners and held on 28 November 2014 to allow interested parties to make oral submissions.

The ACCC has considered the submissions provided by Medicines Australia and interested parties. Based on the information before it, the ACCC proposes to amend the individual reporting requirement to ensure all relevant transfers of value are reported. The ACCC also proposes to impose conditions to require a common reporting format that is accessible, to require Medicines Australia to use reasonable endeavours to implement a centralised reporting system and to report regularly on progress, and to require publication and retention of reports for three years instead of two. The ACCC is also proposing a procedural condition in respect of future non-material amendments to the conditions. The ACCC is not proposing to impose conditions in relation to ongoing food and beverage reporting or drug name reporting

at this time. The ACCC has provided detail below on its proposed approach and is seeking feedback from Medicines Australia and interested parties.

Proposed Conditions

Reporting of all transfers of value

In the draft determination, the ACCC noted its concern that, under edition 18 of the Code as currently drafted, member companies will not be required to publish information about a relevant transfer of value made to a healthcare professional individually if the healthcare professional does not consent to have information about that transfer of value reported (such transfers would instead be reported in aggregate).

The ACCC proposed a condition in the draft determination requiring Medicines Australia to amend the Code to require members, prior to making a relevant transfer of value, to either (i) obtain the consent of a healthcare professional to the disclosure of information, or (ii) take appropriate steps to give notice of the disclosure obligation so that the healthcare professional would reasonably expect the disclosure.

The ACCC intends to impose this condition, subject to two further changes described below (see also the draft condition and proposed amendments to the Code at [Attachment A](#)).

Concerns have been raised that the condition proposed in the draft determination allows a healthcare professional to provide consent at the time of receiving a transfer of value and to later withdraw it prior to publication. This would not allow the transfer to be reported individually. Given these concerns, the ACCC proposes to remove option (i) (i.e., obtaining consent) from the condition.

Medicines Australia submits that the changes to the transparency regime are significant and should not be rushed. It proposes that the transparency regime currently contained in edition 18 of the Code should be allowed to be implemented for a 12 month period from 1 October 2015 to 1 October 2016, with the amendments required by the ACCC's proposed condition in Attachment A coming into effect on 1 October 2016.

The ACCC is proposing to allow this extension but expects Medicines Australia to prepare for this change in advance to ensure it meets this timeframe.

Format for reporting all individual transparency data

As discussed below, Medicines Australia is investigating how to establish a centralised database for reporting the individual transparency data. However Medicines Australia expects this to take some time.

The ACCC is proposing to impose a condition of authorisation requiring Medicines Australia to amend the Code to require member companies to report the individual transparency data in a standard template and in an identical accessible format (see draft condition at [Attachment B](#)). This would ensure that the data is reported in an accessible format even before a centralised database is introduced. The ACCC is proposing to require reports to be formatted using Microsoft Excel, however it welcomes submissions about the merits of alternative reporting formats.

Implementation of a centralised database for reporting individual transparency data

In light of the submissions and additional information received, the ACCC is proposing a condition of authorisation with respect to implementing a centralised database. The ACCC considers that such a database will be an important part of the

reporting regime, by providing a practical way to access the individual transparency data.

Medicines Australia has submitted that it and its member companies are actively investigating how to establish a central platform for reporting individual transfers, but there remain outstanding issues to address. A number of parties support the timely introduction of an accessible centralised database for reporting.

In its draft determination, the ACCC sought submissions on the practical issues and timing for implementing such a database. Medicines Australia and interested parties expressed similar views to those put prior to the draft determination.

The ACCC is proposing a condition that would require Medicines Australia to use reasonable endeavours to develop and implement a centralised database and to periodically report on progress and steps taken towards implementation (see draft condition at [Attachment C](#)).

While the ACCC is not proposing to impose a condition that would require the centralised database to be implemented within a specified timeframe, the status of the centralised database at the time of seeking any reauthorisation will be a significant factor in the ACCC's assessment of that application.

Public disclosure of reports and retention of records for three years

The Code requires member companies to publish the individual transparency data on their websites for two years from the date of first publication.

Some interested parties consider data should be retained for a longer period, such as five or seven years. Medicines Australia queries the utility or need for the information to exist beyond two years and notes that the data relates to personal information.

The ACCC is proposing a condition that would require this information be published for three years (see [Attachment D](#)).

Amendment of conditions

The ACCC is proposing to include a condition that would enable Medicines Australia to request non-material amendments to the conditions and enable the ACCC to decide to make such amendments (see draft condition at [Attachment E](#)). Non-material amendments to the conditions may include amendments to address practical issues that may arise with the implementation of, and compliance with, the conditions from time to time.

Matters in respect of which no condition is to be imposed

Food and beverage reporting

Edition 18 of the Code discontinues the reporting of food and beverages provided in connection with educational events, consultancies and advisory boards that was required by edition 17 of the Code; instead it imposes a cap of \$120 per meal.

Interested parties have expressed concerns with the discontinuance of this transparency reporting.

Medicines Australia has consistently opposed continuing food and beverage reporting on the basis it would be administratively burdensome and impose large compliance costs for member companies 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.

Medicines Australia submits that the new transparency reporting regime will capture the majority of interactions with healthcare professionals that include the provision of

food and beverages. Medicines Australia also estimates that 68% of the current reportable amount provided by member companies to healthcare professionals will continue to be reported under edition 18 of the Code (the estimated 32% that will be unreported is comprised of food and beverages, as well as costs such as room/AV hire and transfer costs).¹

In the draft determination, the ACCC identified the possible need for a condition requiring some form of continuing transparency around the provision of food and beverages, given the potential conflict of interest that can arise. The ACCC posed several possible options to address this issue.

The ACCC has continued to consider this issue following the draft determination and accepts that:

- food and beverage costs are secondary to the larger and more direct transfers of value;
- the individual transparency model is designed to focus on these more direct transfers of value;
- the \$120 cap on meals introduced in edition 18 will go some way in ensuring that expenditure on food and beverages is not inappropriate; and
- the administrative burden of reporting food and beverage expenditure, in addition to the new individual transparency regime, would be significant.

The ACCC is therefore not proposing to impose a condition in the final determination requiring ongoing food and beverage reporting.

The ACCC is concerned however to ensure that all relevant required expenditures are reported and that such expenditures are not categorised incorrectly as food and beverage expenditure (and therefore not reported under the new regime). If food and beverage expenditure was to increase significantly upon cessation of the existing transparency reporting, it may suggest some expenditure is not being categorised correctly. The ACCC therefore expects Medicines Australia, when seeking any reauthorisation, to provide data on expenditure trends for food and beverage during the period of this authorisation. If the data indicates that there has been an increase in this expenditure, the ACCC may reconsider its position in relation to food and beverage reporting.

Reporting of drug names

The ACCC has decided to not impose a condition in respect of this issue at this time but expects Medicines Australia, prior to any application for reauthorisation, to take steps to prepare for the possible inclusion of drug names, where relevant, in the individual transparency reporting data.

Whether breaches of the Code should be better publicised

The ACCC has decided to not impose a condition in respect of this issue at this time but expects Medicines Australia, prior to any application for reauthorisation, to look at ways to better publicise breaches of the Code.

¹ Based on a review of data in the current reports.

Call for comments

The ACCC seeks comments from Medicines Australia and interested parties regarding the proposed conditions. The ACCC seeks submissions by **COB 20 February 2015**.

Next steps

Following consultation on the proposed conditions of authorisation, the ACCC will proceed to release a final decision on this matter. The ACCC anticipates releasing its final determination in March/April 2015.

A copy of this letter has been placed on the ACCC's public register. If you wish to discuss any aspect of this matter, please do not hesitate to contact Tess Macrae on (03) 9290 1835 or Darrell Channing on (02) 6243 4925.

Yours sincerely

A handwritten signature in black ink, appearing to be 'Rami Greiss', written in a cursive style.

Rami Greiss
Executive General Manager
Merger and Authorisation Review Division

Attachment A: Reporting of all relevant transfers of value

The ACCC requires Medicines Australia to vary the Code, by amending section 41.3.2 as follows, with such amendment to take effect on or before 1 October 2016:

- a. deleting the title 'Informed Consent' and replacing it with the following:

'Requirements for Making and Reporting Transfers of Value to Healthcare Professionals';

- b. deleting the words '*informed consent and*' from the second sentence of the first paragraph; and

- c. deleting the second paragraph and replacing it with the following:

'Companies must not make a transfer of value of a kind referred to in section 41.3.1 unless they have taken appropriate steps to give notice of this disclosure obligation, so that the healthcare professional would reasonably expect the disclosure.'

41.3.2 ~~Informed Consent~~ Requirements for Making and Reporting Transfers of Value to Healthcare Professionals

Companies must comply with Australian Privacy legislation (Privacy Act 1988 (C'th)) in regard to the reporting of individual healthcare professional data. Each company must establish a means to ensure ~~informed consent and~~ maintenance of records which comply with Australian Privacy legislation.

~~Where recipients of transfers of value cannot be identified for legal reasons, the amount attributable to such transfers must be reported on an aggregate basis by each company. The number of recipients involved must be stated and the aggregate amount attributable to transfers of value to such recipients.~~

Companies must not make a transfer of value of a kind referred to in section 41.3.1 unless they have taken appropriate steps to give notice of this disclosure obligation, so that the healthcare professional would reasonably expect the disclosure.

Attachment B: Reporting in common accessible format

The ACCC requires Medicines Australia to vary the Code by amending before 1 October 2015:

- a. the fifth paragraph of section 41.3 as follows:

deleting the words '*The form of reporting must follow the template provided in the Code of Conduct Guidelines*', and replacing with the following:

'The reporting must be in Excel format and in strict accordance with the template provided in the Code of Conduct Guidelines.'

- b. the third paragraph of section 41.3.1 as follows:

deleting the words '*Companies are required to report transfers of value in accordance with the template provided in the Code of Conduct Guidelines for Edition 18.*', and replacing with the following:

'Companies are required to report transfers of value in Excel format and in strict accordance with the template provided in the Code of Conduct Guidelines for Edition 18.'

Attachment C: Centralised database

Medicines Australia must:

- a. upon the authorisation taking effect, use reasonable endeavours to develop and implement a system which will allow the public to access, via a single, searchable source available on the internet, the information contained in the reports of all member companies described in section 41.3.1 (**Central Reporting System**);
- b. within six months of the authorisation taking effect, and at least every six months thereafter until the implementation of a Central Reporting System in accordance with (d) below:
 - i. publish a report in the Code of Conduct section of its website identifying the steps taken by Medicines Australia during that reporting period to develop and/or implement a Central Reporting System;
 - ii. notify the ACCC upon the report referred to in (i) above being published;
- c. prior to implementing a Central Reporting System, amend the Code by inserting the following words into section 41.3:

'Companies must provide the reports referred to in section 41.3.1 to Medicines Australia or a third party nominated by Medicines Australia within two months of the reporting period to which they relate.'

- d. upon implementation of a Central Reporting System and while the authorisation remains in effect:
 - i. ensure that all reports referred to in (c) above are included in the Central Reporting System within four months of the end of the reporting period to which they relate;
 - ii. maintain and update the Central Reporting System; and
 - iii. ensure that information contained in the Central Reporting System remains accessible by the public for a period of at least three years.

Attachment D: Public disclosure of reports and retention of records for three years

The ACCC requires Medicines Australia to vary the Code by amending before 1 October 2015 section 41.3.4 by deleting the word 'two' and replacing with the word 'three'.

Attachment E: Amendment of conditions

- a. Medicines Australia may apply in writing to the ACCC for a non-material amendment to these conditions.
- b. Such applications must:
 - i. state the nature of, and reasons for, the amendment sought;
 - ii. be accompanied by supporting evidence.
- c. The ACCC may request from Medicines Australia any additional information required by the ACCC to assess the application for amendment.
- d. The ACCC will consider the application for amendment and, in its absolute discretion, decide whether or not to make a non-material amendment to the conditions and the nature and form of any amendment. The ACCC will notify Medicines Australia, in writing, of its decision.
- e. If the ACCC decides to amend the conditions, the amendment will take effect from a date determined by the ACCC.