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20 February 2015

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**

Medicines Australia welcomes the opportunity to respond to the ACCC's proposed conditions on authorisation of Edition 18 of the Medicines Australia Code of Conduct. Medicines Australia is broadly supportive of those conditions, subject to the comments below.

1 Format for reporting transparency data: Attachment B

1.1 Reporting template should only set minimum standard

The ACCC has suggested amending sections 41.3 and 41.3.1 of the Code to require transparency reporting to be in 'strict accordance' with the template provided in the Code Guidelines. While Medicines Australia accepts a requirement that those sections refer to data being disclosed 'in accordance' with the template, it considers that the word 'strict' should not be included in those sections as such an amendment will have the unplanned consequences set out below.

The Code already contains prescriptive requirements in section 41.3.1 describing what data must be reported, as a minimum. These are:

- date of the event or provision of service;
- healthcare professional's name;
- type of healthcare professional (i.e. medical practitioner, pharmacist, nurse practitioner);
- healthcare professional's principal practice address;
- description of the service (i.e. speaker, Advisory Board member, Chairperson at educational meeting etc);
- description of the event (i.e. company sponsored meeting in Australia; independent meeting held in Australia; independent meeting held overseas; etc);
- whether the payment was made to the healthcare professional or a third party; and

Our Ref FVCS:CHBS:206029656
chbs A0132160200v1 206029656 23.01.2015

- the amount of the payment or transfer of value, subdivided into (where relevant) registration fees, travel and accommodation, and fees for service.

Including the term 'strict' in sections 41.3 and 41.3.1 suggests that member companies cannot provide any **additional** information when publishing transparency data, such as explanatory information on the education provided. Such information could help consumers understand the nature of the relationship between the member company and the healthcare professional.

Further, one rationale for including a reporting template in the Code of Conduct Guidelines was to allow Medicines Australia to improve and refine the report format once member companies gain experience reporting transfers of value under the new system. Requiring publication in 'strict' accordance with the existing template would mean Medicines Australia could not make such improvements.

Even if Medicines Australia were to amend the reporting template:

- the data included in the report would not change because the Code contains detailed requirements on what data must be published; and
- being able to include an additional field in the reporting template with further information should not affect any potential centralised database provider's ability to publish data in the future if a database is established, as that entity could simply delete the additional field when collating the data.

Accordingly, the reporting template should only dictate the minimum standard required.

1.2 Excel format is not appropriate

Medicines Australia does not support a requirement that the transparency reports be provided in Excel format. There are several reasons for this:

1 Compliance with the Australian Privacy Principles

Pursuant to Australian Privacy Principle 11, if Medicines Australia (or its member companies) holds personal information, it must take 'such steps as are reasonable' to protect the information from:

- misuse, interference and loss; and
- unauthorised access, modification or disclosure.¹

Medicines Australia is concerned that publishing a healthcare professional's personal data in Excel format will affect the security of the data. Third parties would be able to access, disclose (that is, re-publish), extract and potentially modify the information, and to do so for purposes unrelated to those for which the data was collected.

Accordingly, Medicines Australia is concerned that a requirement to publish data in Excel format could prohibit it, and member companies, from complying with the Australian Privacy Principles. In this regard, Medicines Australia also notes that there is a substantial difference between publishing aggregate data (which is not personal information) in a form that can be extracted, modified or disclosed by third parties and publishing personal information in such a format.

Medicines Australia respectfully considers that it would be appropriate for the ACCC to seek the Privacy Commissioner's views on a requirement for member companies to publish individual healthcare professionals' personal information in Excel.

¹ Australian Privacy Principles: *Privacy Act 1988* (Cth) Schedule 1.

In any event, Medicines Australia notes that the purposes for individual disclosure identified in the ACCC's Draft Determination will still be satisfied if the information is published in a format that does not allow the data to be extracted and modified (such as a readable and searchable PDF). In the Draft Determination on Edition 18 the ACCC stated the benefits of individual reporting as:

- having the potential to address the principal-agent problem by giving patients some transparency over a matter which may influence the objectives of their prescribing healthcare professional: at [133];
- being aware of transfers of value received by a particular healthcare professional may alert a patient to a possible influence on their healthcare professional's prescribing decisions, and enable the patient to explore this further: at [134];
- enabling fellow healthcare professionals to inform themselves about matters which may be relevant to their understanding of, for example, a key opinion leader in their field: at [135]; and
- deterring member companies from making, and healthcare professionals from accepting, transfers of value which are inappropriate or which may raise conflicts of interest, if the transfers are subject to public scrutiny: at [135].

If the relevant information is published in say, searchable PDF form, individual patients (and healthcare professionals) will have access to sufficient data to meet the purposes articulated above, while ensuring that the integrity of the personal information is protected from inappropriate use.

2 Stifling future development

Medicines Australia is also concerned that specifying a particular format for reporting may serve to dissuade members from using or developing other disclosure platforms which could provide a greater ability for individual patients to search for information on their healthcare professional. In this regard, Medicines Australia is aware of one member company who has expressed an intention to provide the relevant transparency data in a different format to Excel but one which nevertheless allows the data to be effectively searched and also tabulated/summarised, without that data being able to be modified or extracted by a third party.

This issue is of particular concern in circumstances where the ACCC proposes to authorise Edition 18 of the Code for a period of five years and where there may be technological advances during this period that will enable data to be published and disclosed using different software programs or in different formats to those currently available.

3 Requirement to use a specified program

Medicines Australia considers that its member companies will express surprise and concern that the ACCC is requiring them to use a particular proprietary software program.

In the event that the ACCC has any residual concerns to ensure the reports are easily searchable, Medicines Australia submits that the proposed condition should be phrased in a technology neutral way. For example, the proposed condition could be amended to specify only the criteria/attributes that the format must fulfil, for example, 'reporting must be in a form that is easily accessible and searchable by patients'. In this regard, Medicines Australia notes that other jurisdictions such as the US and the UK do not require data to be published in a specific way, but simply provide that the method of publication have certain qualities.

2 Implementation of a centralised database: Attachment C

Medicines Australia reiterates its concerns and the issues raised in previous submissions regarding the legal, technical and market equality challenges of establishing a centralised database. Medicines Australia will, however, investigate and consult with other stakeholders about how a centralised database could be established.

Paragraph (c) of Attachment C requires that, should a centralised database be implemented, Medicines Australia must amend section 41.3 of the Code to require member companies to provide the relevant reports to Medicines Australia or a third party 'within two months of the reporting period to which they relate'.

Medicines Australia has two concerns with the current drafting of paragraph (c):

- Medicines Australia understands that the intention of paragraph (c) is to enable Medicines Australia to make an amendment to the Code in the future, if a centralised database is established, to require member companies to submit the transparency reports to Medicines Australia so that they can then be included in that database.

Paragraph (c) as currently worded could be read as requiring Medicines Australia to itself publish those reports (which it is not currently required to do under the Code). Medicines Australia therefore recommends that the wording be amended to ensure that there is no ambiguity by, for example, stating that: 'Companies must provide the reports... to Medicines Australia or a third party nominated by Medicines Australia so that the data in those reports can be included in a Central Reporting System...'

- The proposed wording in paragraph (c) also requires companies to provide the relevant reports 'within two months of the reporting period to which they relate'. In circumstances where section 41.3.3 of the Code requires companies to provide healthcare professionals with six weeks to review information collected about them and to submit any corrections to that information, it will not be possible for member companies to collate and prepare the data, send it to healthcare professionals for review and receive and process any corrections within two months (essentially eight weeks).

Medicines Australia recommends that the proposed condition be amended to provide that companies provide the reports within 'four months of the end of the reporting period', in line with the current requirements in the Code.

Relevant to this, Medicines Australia strongly submits that it is not appropriate for the ACCC to, at this stage, specify in paragraph (d)(i) of the proposed condition at Attachment C a requirement that the **centralised database provider** publish the data within a specific time period (four months). Without knowing which entity will be running the centralised database if established, or the form of that database, it is not possible to know how much time a database provider will need between receiving the data from a member company and being able to publish that data. A database provider may need to, for example:

- reprocess or format the data in some way;
- allocate a unique identifier to each healthcare professional so that their data may be collated; and
- review data provided by multiple members in order to ensure that data is collated appropriately so that it is attributed to the correct healthcare professional eg where one healthcare professional receives a transfer of value from more than one member company, making sure all relevant data are allocated correctly for that healthcare professional.

In other jurisdictions which require publication of transparency data through a centralised database a significantly longer period than four months from the end of the data collection period is provided for:

- Under the applicable UK code no healthcare professional verification of data occurs. Regardless, the code provides for a period of six months from the end of the collection period to the date of publication.
- Under the US Physician Payments (Sunshine) Act, a period of 90 days between the end of the collection period and submission to the CMS (the database manager) is specified. After the 90 day period an additional 45 day period is then allowed in which healthcare professionals may review and seek correction of the information relating to them. The CMS **then** publishes the data. However, there is no statutory time frame in which the CMS is required to publish the data. For the first data collection period which ended on 31 December 2013, the CMS did not publish the data until 30 September 2014.

Once the questions surrounding the establishment of a centralised database are further progressed, Medicines Australia can provide the ACCC with an estimate of the time that a database provider is likely to need in order to publish accurate data, if a centralised database is established. Medicines Australia will do this as part of its regular updates to the ACCC regarding the database.

3 Food and beverage reporting

The ACCC has stated that it expects Medicines Australia, when seeking reauthorisation, to provide data on expenditure trends for food and beverages during the period of authorisation. The ACCC has expressed a concern that: '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'.

Medicines Australia is concerned that requiring it to provide data on expenditure 'trends' will essentially require member companies to continue to record the hospitality reporting data which was originally proposed by the ACCC in the Draft Determination, and which the ACCC has determined is a 'significant administrative burden'. Without taking detailed steps to record food and beverage expenditure, Medicines Australia's members will not be able to supply it with the data required to analyse trends.

The requirement therefore serves as a *de facto* food and beverage reporting condition.

The ACCC's letter of 6 February suggests that the request to provide such data is essentially to assist the ACCC to ensure that member companies do not incorrectly categorise expenditure as food and beverages in order to avoid the transparency reporting requirements. In response to this Medicines Australia notes that:

- the Code is explicit as to which types of expenditure must be recorded and published. It is difficult to see how, for example, travel and accommodation costs could be incorrectly categorised as food and beverage costs in order to avoid reporting;
- section 41.3 of the Code provides a requirement that the most senior executive officer of the company (such as the Managing Director) provide to Medicines Australia a signed and dated declaration that the company has published the relevant transparency report on the company's website and that the report **includes all payments and transfers of value required under Section 41.3.1**. The declaration must be provided to Medicines Australia within seven calendar days following the publication of each report. Member companies take compliance with the Code seriously, and this declaration ensures that a senior member of

the company has considered the company's compliance with the Code when publishing data;

- member companies have an exemplary record of accurately reporting event expenditure and there is no suggestion that this will change under the new regime. In this regard, member companies have strong compliance cultures arising from, among other things, frequent internal and external audits in respect of their accounting practices (both as Australian entities and as subsidiaries of large multi-national pharmaceutical companies). Member companies are highly unlikely to deliberately categorise a transfer of value incorrectly to avoid disclosing data under the Code in circumstances where they take their compliance obligations seriously;
- Medicines Australia is aware of no evidence to suggest that member companies are increasing their expenditure on food and beverages; and
- as set out in Medicines Australia's submission of 20 January 2015, providing general trend data on food and beverage expenditure will fail to allow the public to interpret any trends relating to such expenditure in any event. This is because annual changes would not take into account any growth or contraction trends in the industry overall, the growth in size of individual companies or their product portfolio (several member companies may have introduced multiple new medicines to the Australian market in one given year, requiring additional education on those products) or the decline in size of member companies (following, for example, patent expiry). Providing crude trending data would therefore be of little or no practical benefit and would certainly not provide an accurate measure by which the ACCC could determine that some expenditure was not being categorised correctly (and therefore not reported).

Feel free to contact us if you would like to discuss any matter raised in this submission.

Yours sincerely

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