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9 April 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

The purpose of this letter is to provide information in support of Medicines Australia's view that member companies should not be required to provide transparency reports in both a searchable table format and a CSV file format.

1 Introduction

The ACCC has indicated that it intends to impose a condition that would require reporting by member companies of healthcare professionals' transparency data in a common accessible format. The condition is similar to the draft version released on 6 February 2015, however it requires reporting in a CSV file format (***Proposed Condition***). The ACCC's drafting of the Proposed Condition is as follows:

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 use a CSV file format capable of being supported by spreadsheets and database management systems including Microsoft Excel and be in a table format in accordance with the template provided in the Code of Conduct Guidelines, sorted alphabetically by each healthcare professional's family name, then by first name, then by middle initial, then by event date.'

- 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 using a CSV file format capable of being supported by spreadsheets and database management systems including Microsoft Excel and be in a table format in accordance with the template provided in the Code of Conduct Guidelines for Edition 18, sorted alphabetically by each

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healthcare professional's family name, then by first name, then by middle initial, then by event date.'

Medicines Australia does not support a requirement that member companies publish transparency reports in both a searchable table format and a CSV file format for the following reasons:

- publishing the information in a searchable table form will provide sufficient data to result in the benefits of individual reporting articulated by the ACCC in its Draft Determination. Reporting in a CSV file format, in addition to a searchable table format, is unnecessary; and
- a requirement to report in a CSV file format could prohibit Medicines Australia and its member companies from complying with the Australian Privacy Principles.

Further, the Proposed Condition as currently drafted is ambiguous; it could be interpreted as requiring that the transparency reports be published in a table format as a CSV file, as opposed to both a searchable table format *and* a CSV file. Medicines Australia's suggested amendments to the wording of the Proposed Condition, should the ACCC be minded to impose the Proposed Condition on authorisation, are set out in section 3 below.

2 Reports should be made available in a searchable format but not in a CSV file format

Medicines Australia accepts that all member companies will publish payments and transfers of value made to all healthcare professionals for a given six month period in a searchable format in accordance with the template provided in the Code of Conduct Guidelines for Edition 18. However, Medicines Australia does not support a requirement that member companies also provide the transparency reports in a CSV file format for a number of reasons.

2.1 Sufficient data will be provided in a searchable and readable format

Medicines Australia considers that reporting in a CSV file format, in addition to a searchable table format, is unnecessary. The benefits for individual disclosure identified in the ACCC's Draft Determination will be achieved if the information is published in a searchable table 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 of the Code 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];
- alerting a patient to a possible influence on their healthcare professional's prescribing decisions by informing the patient of transfers of value received by a particular healthcare professional. This enables the patient to explore the matter further, should they wish to do so: 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 table form, individual patients (and healthcare professionals) will have access to sufficient data formatted in a readable and user-friendly way to result in the benefits articulated above, while ensuring that the integrity of the healthcare professionals' personal information is protected from inappropriate use and modification.

In addition to being unnecessary, CSV file formats do not present data in a meaningful, readable and user-friendly way. CSV file formats do not retain formatting, formulas or worksheets, resulting in a file containing a large amount of data that is unformatted, contained in one worksheet, and which contains 'values' rather than formulas (meaning that formulas would have to be recreated every time the file is opened). For this reason, publishing reports in a CSV file format will not assist the achievement of the benefits expressed above; instead, patients and other health care professionals would encounter an incomprehensible 'dump' of data.

2.2 Compliance with the Australian Privacy Principles

Medicines Australia is concerned that a requirement to publish data in a CSV file format could prohibit it, and member companies, from complying with the Australian Privacy Principles (**APP**). This is because publishing a healthcare professional's personal information in a CSV file format cannot be considered to be for a purpose related to that for which the data was collected.

The Australian Privacy Commissioner, in his letter of 26 March 2015, stated that a member company can only use or disclose personal information in accordance with APP 6. That is, personal information can only be used or disclosed where it is for a purpose related to the primary purpose of collection and the individual would reasonably expect their information to be used or disclosed for that purpose.

The purposes for which member companies collect information for individual disclosure are articulated in section 2.1. As outlined above, publishing transparency reports in a CSV file format, due to the nature of the file, would not inform consumers or healthcare professionals about transfers of value which are inappropriate or which may raise conflicts of interest. This will be achieved by publishing data in a searchable table format, such as a searchable PDF form. As a result, if member companies disclose healthcare professionals' personal information in a CSV file format, they will be at risk of contravening APP 6 by disclosing the information for a purpose unrelated to that for which the data was collected.

For this reason, Medicines Australia considers that member companies should not be required to publish transparency reports in a CSV file format. In the event that the ACCC has any residual concerns to ensure the reports are easily searchable, Medicines Australia again 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 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 UK do not require data to be published using specific proprietary software, but simply provide that the method of publication have certain qualities with respect to searchability.

3 Drafting of the Proposed Condition is ambiguous and open to interpretation

Medicines Australia is concerned that the ACCC's Proposed Condition, as currently drafted, is ambiguous; it could be interpreted as requiring that the transparency reports be published in a table format as a CSV file, as opposed to both a searchable table format and a CSV file.

Should the ACCC be minded to impose the Proposed Condition on authorisation, for the avoidance of doubt Medicines Australia suggests the Proposed Condition is drafted as follows:

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 the following formats:

