

Proposed amendment 1

Amend Section 41.3.2, effective from 1 October 2016, to remove the requirement for Informed Consent and replace it with the requirement to establish the reasonable expectation of the disclosure obligation. The following text to be inserted in the Code immediately following Section 41.3.2 Informed Consent:

Effective from 1 October 2016, Section 41.3.2 Informed Consent is replaced in its entirety by the insertion of the following revised section:

Section 41.3.2 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 maintenance of records which comply with Australian Privacy legislation.

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.

The revised Section 41.3.2 will read (inserted text in red):

41.3.2 Informed Consent

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.

Effective from 1 October 2016, **Section 41.3.2 Informed Consent** is replaced in its entirety by the following revised section:

41.3.2 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 maintenance of records which comply with Australian Privacy legislation.

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.

Proposed amendment 2

Amend the fifth paragraph of Section 41.3 by the deletion of the words “The form of reporting must follow the template provided in the Code of Conduct Guidelines.” and the insertion of the following text in place of those words:

Companies are required to report transfers of value in the following formats:

- i. a searchable table to be viewed on a company’s website; and
- ii. a CSV file available for download from the company’s website capable of being supported by spreadsheets and database management systems including Microsoft Excel,

formatted in accordance with the template provided in the Code of Conduct Guidelines, in which the data is sorted alphabetically by each healthcare professional’s family name, then by first name, then by middle initial, then by event date.

The revised paragraph of Section 41.3 will read (revised text in red):

Each company must report on its own website the reports described under Section 41.3.1. The initial reports covering the period 1 October 2015 to 30 April 2016 must be published on companies’ websites by 31 August 2016 and every 6 months thereafter.

Companies are required to report transfers of value in the following formats:

- i. a searchable table to be viewed on a company’s website; and
- ii. a CSV file available for download from the company’s website capable of being supported by spreadsheets and database management systems including Microsoft Excel,

formatted in accordance with the template provided in the Code of Conduct Guidelines, in which the data is sorted alphabetically by each healthcare professional’s family name, then by first name, then by middle initial, then by event date.

Medicines Australia will provide hyperlinks to each company’s report from its website.

Proposed amendment 3

Amend the third paragraph of Section 41.3.1 by the deletion of 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 the insertion of the following text in place of those words:

Companies are required to report transfers of value in the following formats:

- i. a searchable table to be viewed on a company’s website; and
- ii. a CSV file available for download from the company’s website capable of being supported by spreadsheets and database management systems including Microsoft Excel,

formatted in accordance with the template provided in the Code of Conduct Guidelines, in which the data is sorted alphabetically by each healthcare professional’s family name, then by first name, then by middle initial, then by event date.

The revised paragraphs of Section 41.3.1 will read (inserted text in red):

Where healthcare professionals request a payment for any of the above to be made to a third party, these payments must still be disclosed for the individual healthcare professional, however, the report should identify that payment was made to a third party.

Companies are required to report transfers of value in the following formats:

- i. a searchable table to be viewed on a company’s website; and
- ii. a CSV file available for download from the company’s website capable of being supported by spreadsheets and database management systems including Microsoft Excel,

formatted in accordance with the template provided in the Code of Conduct Guidelines, in which the data is sorted alphabetically by each healthcare professional’s family name, then by first name, then by middle initial, then by event date.

Proposed amendment 4

Amend Section 41.3.4 by the deletion of the word “two” and replacing it with the word “three”.

The revised Section 41.3.4 will read (amended text in red):

41.3.4 Period of public disclosure of reports and retention of records

The information disclosed in accordance with Section 41.3.1 must be published on companies’ websites for **three** years from the date of first publication.

Proposed amendment 5

Amend Section 9.1 by inserting the following paragraph as the fourth paragraph in that section:

The maximum cost of a meal (including beverages) stated in Section 9.4.3 applies to all situations where a meal is provided to a healthcare professional within Australia. It applies to Advisory Board meetings, consulting arrangements or any other situation where a meal is provided by a company to a healthcare professional.

The revised Section 9.1 will read (inserted text in red):

9.1 General Principles

Companies may choose to support, initiate or become involved in activities with healthcare professionals. Such involvement either by financial or other means must be able to successfully withstand public and professional scrutiny, and conform to professional and community standards of ethics and good taste.

Interactions with healthcare professionals must have the primary objective of enhancing medical knowledge and improving the quality use of medicines in Australia.

No financial or material benefits should be conditional upon any obligation by the healthcare professionals to recommend, prescribe, dispense or administer a company's prescription product(s).

The maximum cost of a meal (including beverages) stated in Section 9.4.3 applies to all situations where a meal is provided to a healthcare professional within Australia. It applies to Advisory Board meetings, consulting arrangements or any other situation where a meal is provided by a company to a healthcare professional.

Proposed amendment 6

Amend Section 41.2.1 by the deletion of the words "first report covers the period 1 October 2014 to 31 March 2015 and the last" in the second paragraph following the heading Advisory Boards Report, such that the amended paragraph reads as follows:

Under Edition 18 of the Code the required report covers the period 1 April 2015 to 30 September 2015.

In addition, amend Section 41.2.1 by the insertion of the following paragraph as the third paragraph following the heading Advisory Board Report:

The report must be submitted to Medicines Australia by 30 October 2015.

The revised subsection of Section 41.2.1 will read (amended and inserted text in red):

Advisory Boards Report

The completed table for Advisory Boards must include details for each Advisory Board: the number of members, honoraria/sitting fees, costs of any hospitality, accommodation (both within and outside Australia) and travel, venue details and third party costs. The names of the participants need not be disclosed.

Under Edition 18 of the Code the required report covers the period 1 April 2015 to 30 September 2015.

The report must be submitted to Medicines Australia by 30 October 2015.

Medicines Australia will make publicly available on its website the completed tables provided by each Member Company within two months of receiving the reports.