

## **Detailed Summary of Amendments Included in Code of Conduct Edition 18**

**The following summarises the amendments included in Edition 18 of the Code.**

All references to other publications, such as TGA guidelines, have been updated.

### **Introduction**

- Inclusion of proactive statement about commitment to transparency and how the industry interacts with healthcare professionals.
- Amendment of description of the relationship between the Code and Medicines Australia's Constitution.

## **1. Nature and Availability of Information and Claims**

### 1.1 Responsibility

- Additional information on achieving balance by inclusion of safety and precautionary information in relation to efficacy or other promotional claims.

### 1.4 Unapproved Products and Indications

- Inclusion of a mechanism to permit companies to make information available about unapproved products and/or indications via a medical information website. This website may not be promoted to healthcare professionals (HCPs). It cannot include advertising or promotional information.

### 1.7 New Products

- Clarification that promotion of a product that will be available via the PBS, RPBS, NIP or LSDP may only occur after written advice is received from the Department of Health stating the listing date.

## **2. Promotional material directed at healthcare professionals**

- Primarily editorial changes.

### 2.2 Electronic and Audiovisual Media including electronic Detail Aids (e-Detail Aids)

- A new requirement that text that is given prominence in printed forms of promotional materials, such as PBS information, qualifying statements and referring the prescriber to review the Product Information, should be similarly prominent by text size and location in electronic and audio-visual media.

### 2.4.1 Advertisements for healthcare professionals on Company controlled websites and in independent e-journals and e-Newsletters

- Equivalent requirement to that made in Section 2.2 (above) relating to prominence of text in electronic forms of advertisements.

## **3. Types of Product Information**

### 3.2 Minimum Product Information

- A new explicit requirement, reflecting current practice, that the Minimum Product Information must be reviewed and, where necessary, updated in a timely manner following a change to the Product Information.

### 3.3 Changes of clinical significance

- Removal of the requirements for the manner in which a change of clinical significance is communicated to HCPs.
- Addition of a requirement, consistent with TGA requirements, that companies must communicate a change to the Product Information in accordance with any direction from the TGA.

### **4. Educational Material directed at Healthcare Professionals**

- Editorial changes only.

### **5. Company Representatives - Roles and ethical conduct**

- No changes.

### **6. Company Representatives - Training**

- No changes.

### **7. Product Starter Packs**

- Editorial amendments to ensure the Code is consistent with State and Territory requirements for distribution of starter packs, including retention of records for supply of starter packs for a minimum of 2 years unless a longer period is required by State or Territory legislation.
- Section 7.8 – addition of requirement that the Company should supply pre-printed adhesive labels that comply with the Standard for the Uniform Scheduling of Medicines and Poisons, Appendix L, and which provide sufficient space for the relevant details to be entered by the dispensing healthcare professional.

### **8. Product Familiarisation Programs (PFP)**

- Addition of a requirement for the patient information document (a current requirement of the Code) to include a section for the patient to sign indicating their consent to receive the product under the terms described in the patient information document. This consent is to be retained by the healthcare professional and is not to be returned to the company.
- New provision to allow trade packs to be supplied for patients enrolled in a PFP if the product is dispensed through a pharmacy or other authorised dispensary or dispenser.
- New provision to allow the collection of individual patient data under a PFP if the PFP is set up in a manner that enables the rigorous collection of individual patient data under a formal protocol. The protocol should be reviewed within the company to ensure that patient data collection complies with all relevant guidelines and legislation, particularly with respect to patient consent and data de-identification.
- Addition of a requirement, consistent with current practice, that on request, companies must promptly accept the return of their products supplied under a PFP. Returned stock must be disposed of in an environmentally sound manner according to the requirements in each State or Territory.

### **9. Relationship with healthcare professionals**

#### 9.3 – Educational Events

- A new requirement that Companies must have policies and procedures in place that will ensure that educational events for healthcare professionals comply with the Code, and in particular, the maximum cost of a meal stated in Section 9.4.3.

#### 9.4.3 Meals and beverages & 9.7.7 Sponsorship of Healthcare professionals to attend Educational Events (Australasian and International)

- Inclusion of a maximum limit of \$120 (excluding GST and gratuities) for the cost of a meal (including beverages) provided by a company to a healthcare professional within Australia. This maximum would only be appropriate in exceptional circumstances, such as a dinner at a learned society conference with substantial educational content. In the majority of circumstances, the cost of a meal (including beverages) should be well below this figure. For hospitality in association with overseas educational meetings this maximum and/or local guidelines should be used as a guide.
- Refer also to section 41.3.1 – **Reporting of transfers of value to healthcare professionals**, noting that the transparency model does not require reporting of food and beverages provided to healthcare professionals.

#### 9.4.4 Travel & 9.7.5 Sponsorship to attend an Educational Event (equivalent provisions)

- New requirement that travel to attend a company organised educational meeting, or to attend an international, third party educational meeting, may only be provided in direct association with the educational event/s. Any air travel provided must be by the most practical direct route to and from the educational event/s.
- Refer also to section 41.3.1 – Reporting of transfers of value to healthcare professionals, noting that the transparency model requires reporting of air travel provided to healthcare professionals. The model does not require reporting of airport ground transfers, taxis or parking fees.

#### 9.6 – Trade Displays

- New requirement that the amount paid to the educational meeting organiser for a trade display is regarded as sponsorship and must be reported in the current educational event reports (until 30 September 2015) (section 41.2.2) and then from 1 October 2015, in the new Sponsorship of Independent Educational Meetings report (section 41.3.5).
- Correction to section 9.6.7(c) to delete reference to travel and accommodation to attend an educational event. Companies may not offer travel and accommodation to healthcare professionals as an incentive to attend their trade displays.

#### 9.7 – Sponsorship of healthcare professionals to attend educational events

- New requirement in section 9.7.7 that the maximum cost of a meal provided by a company to a sponsored healthcare professional when attending an educational event must comply with section 9.4.3 for events held in Australia. For hospitality in association with overseas educational meetings, this maximum and/or local guidelines should be used as a guide.

#### 9.10 - Reporting Payments to Healthcare Professional Consultants and Advisory Board Members

- Section deleted – all reporting requirements moved to Section 41.
- Reporting payments to healthcare professional consultants and Advisory Board members will continue in the same form as Edition 17 of the Code until 30 September 2015. See section 41.2.1 in Edition 18 of the Code.
- From 1 October 2015, airfares, accommodation, sitting fees or consulting fees will be required to be reported in accordance with section 41.3.1 of Edition 18.

## 11. Ghost writing

- Definition of ghost writing amended to recognise that professional medical writers, who disclose their involvement in writing and their funding source, are acceptable, whereas ghost writers are not acceptable.

## 12. Market research with HCPs

- Deletion of sections relating to reporting payments, which are now included in Section 41.2 for market research conducted before 1 October 2015, or 41.3.1 for market research conducted on or after 1 October 2015.

## 13. Relationship with the general public

### 13.1 General Principles

- New requirement that materials for members of the general public, consistent with Section 1.3 of the Code: all information, claims and graphical representations provided to members of the general public must be current, accurate, balanced and must not mislead either directly, by implication, or by omission. All statistics or analyses provided to the general public by companies must be referenced to their source.

### 13.7 Materials for use with patients (Patient aids)

- Moved from position as Section 17, and a definition included. Patient aids explicitly includes mobile media applications.

### 13.8 Disease Education Activities in Any Media

- Addition of clarifying statement that the linking of a disease education activity to a specific prescription product, such as linking to the Product Information or Consumer Medicine Information, would breach Section 13.3 of the Code and the Commonwealth Therapeutic Goods legislation.

### 13.9 Use of the Internet

- Revision of the definition of 'advertisement' to ensure consistency with the Therapeutic Goods Act 1989.
- Addition of text from the Code Guidelines to make it clear that a company website must not directly link disease specific education to the company's prescription products for that condition. Such linkage would be considered to be advertising the prescription medicine, which would be in breach of Section 13.3 of the Code and the Therapeutic Goods legislation.
- Inclusion from the Code Guidelines that a company disease education website must **not** use a product name for its URL.

### 13.11 Market research with the general public

- Inclusion of statement recognising that market research undertaken with patients who have been prescribed a particular prescription medicine may include specific questions about the product as long as the market research is not promotional.

## 14. Relationship with HCOs and patients

- Deletion from this section of the requirement for disclosure of Health Consumer Organisation (HCO) support, which is now included in Section 41.1.1 in Edition 18 of the Code.

## 15. Sponsorship of Individual Patients/HCO Representatives to Attend Third Party Educational Events

- No changes.

## **16. Access to Company Trade Displays at Third Party Conferences**

- No changes.

## **17. Patient Support Programs**

- Addition of explicit requirement, consistent with current practice and TGA requirements, that suspected Adverse Drug Reactions noted during monitoring of a Patient Support Program must be reported to the TGA in accordance with the relevant guidelines.

## **18. Access to Dispensary Data & 19. Discredit to and Reduction of Confidence in the Industry**

- No changes.

## **20 – 24 Administration of the Code**

- This section of the Code has been extensively revised in order to clarify and make explicit the relationship between the Code of Conduct and the Medicines Australia Constitution; and the Medicines Australia Board and the three Committees established under the Code – the Code of Conduct Committee, Appeals Committee and Monitoring Committee.

### 20.1 Acceptance of Complaints

- Inclusion of a discretion to either not accept a complaint, or accept a complaint and defer referral to the Code Committee where substantially the same subject matter is, at the same time, the subject of legal proceedings between the same parties in an Australian court or Administrative Tribunal.

### Sections 21 to 24 – Membership of the Code of Conduct and Appeals Committees & Sections 32 to 34 Membership of the Monitoring Committee

- These sections describing the membership of the Code of Conduct, Appeals and Monitoring Committees have been revised, in consultation with Medicines Australia's legal counsel, to improve their clarity and robustness.
- The only change to the membership of the Committees is the addition of a senior compliance officer as one of the member company representatives that may participate on either Committee.

### 31.2 – Monitoring procedures

- Clarification of the different types of reviews undertaken by the Monitoring Committee.
- Modification of the number of reviews that a company must respond to in a calendar year: A Member Company will only be required to provide promotional materials or information associated with other activities for review by the Monitoring Committee on no more than three occasions within a calendar year. If a Member Company responds to a Monitoring Committee request that it had not distributed any promotional materials or undertaken any activities that are specified in the request, this response will not be counted as one of the three occasions for that company.
- A Member Company will nevertheless be required to respond to a request from the Monitoring Committee for further information concerning a particular educational meeting, Advisory Board meeting, Health Consumer Organisation support or consultancy arrangement.

#### **37.4. Educational Event reporting**

- Section deleted – all transparency reporting requirements have been moved to Section 41.
- Educational Event reports will continue in the same form as required by Edition 17 of the Code until 30 September 2015. See section 41.2.2 in Edition 18 of the Code.
- Member company initiated events where only food and beverages are provided to healthcare professionals (i.e. no travel or accommodation provided) will no longer be reported under Edition 18. However, (a) the cost of any meal (including drinks) provided by a company must be below the defined limit set in section 9.4.3 (\$120 for food and beverages, exclusive of GST) and (b) other requirements relating to the provision of educational events outlined in section 9 of Edition 17 of the Code will continue to apply (eg the requirement in section 9.4.2 that the choice of venue for any event must be able to successfully withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste).
- For other educational events that will be reported, see below.

#### **41. Transparency Reporting**

- All transparency reporting requirements now included under this Section.
- The introduction provides an affirmative statement about transparency.
- The sections preserve the reporting requirements of Edition 17 of the Code until 30 September 2015.
- From 1 October the new requirements for reporting transfers of value to individual healthcare professionals come into effect, as follows:

The following activities would be reported by companies for individual healthcare professionals, by name, with the amount of the payment or transfer of value:

- Consulting fees and/or speaking fees.
- Sponsorship of a healthcare professional to attend an educational event: 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: consulting fees, accommodation and airfares (whether within or outside Australia).
- Fees paid to healthcare professionals in their role as Advisory Board members: sitting fees, accommodation and airfares (whether within or outside Australia).
- Fees paid to healthcare professionals for the purpose of market research ONLY where the identity of the healthcare professional is known to the company.
- Payment of an educational grant or sponsorship to a specific healthcare professional

The following would not be required to be reported:

- Hospitality (food and beverages): The cost of any meal (including drinks) provided by a company must be below the defined limit set in the Code (\$120 for food and beverages, exclusive of GST).
- Airport ground transfers, taxis, parking fees.
- Venue costs (e.g. room and/or audio-visual equipment hire).

Companies will be required to report transfers of value in accordance with the template that will be provided in the Code of Conduct Guidelines for Edition 18. Reporting of all individual transfers of value for each healthcare professional is required, indicating the following information:

- 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;
  - the amount of the payment or transfer of value, subdivided into (where relevant) registration fees, travel and accommodation, and fees for service.
- If a healthcare professional does not agree to the information being disclosed with their name, the expenditure will be reported in aggregate with the number of healthcare professionals it relates to.
  - Companies will provide healthcare professionals for whom they have collected information about payments and transfers of value the opportunity to review and submit corrections to the information. The period provided for review and verification or correction must be at least six weeks.
  - The reporting cycle is a six monthly cycle, except for the initial report, which would cover seven months from 1 October 2015 to 30 April 2016.
  - The report must be published within 4 months following the end of each reporting period.
  - Companies must publish the data about payments and transfers of value on companies' own websites. Medicines Australia will provide hyperlinks from its website to each Member company's report.

#### 41.3.5 - Reporting of Sponsorship of Third Party Educational Meetings and Symposia

- This new report will provide a report of sponsorships of third party educational meetings, where a company has provided monetary sponsorship of a meeting.
- The report will include purchase of space to provide a trade display at an educational event (including if this is the only sponsorship of the event).
- If a company only directly provides hospitality (food and beverages) for an educational meeting, that is the company brings in sandwiches and drinks or similar modest hospitality, this is not reportable. Currently these third party events are reported under section 37.4 of Edition 17 of the Code.

#### **Appendix 1 Guidelines for Complaints – Non-industry Generated Complaints**

- The Secretariat will (always) offer the service of an Independent Facilitator to a non-industry complainant.
- If the offer of an Independent Facilitator is declined the Secretariat will have the discretion to refer the complaint to the Monitoring Committee (permanent members) and request the Committee to advise whether all relevant Sections of the Code have been identified in the complaint. The Monitoring Committee will only identify additional Sections of the Code if there is an obvious omission by the Complainant.

#### **Appendix 2 Medicines Australia Constitution**

- Changes included to ensure consistency with the revised Medicines Australia Constitution.

#### **Appendix 6 Health Consumer Organisation Support Report Format**

- Inclusion of the HCO Support template as an Appendix

## **Glossary**

- Addition of a definition of 'adverse effect', consistent with relevant TGA guidelines
- Addition of a definition of an 'advisory board'
- Deletion of definition of 'clinical tool' (no longer mentioned in the Code)
- Addition of a definition of 'clinical research'
- Addition of a definition of a 'consultant'
- Revision of the definition of 'a healthcare professional', by reference to HCPs being registered to practice in Australia
- Addition of a definition of a 'medical information website', in relation to the additions to section 1.4 of the Code
- Addition of a definition of 'transfer of value'.