

Detailed Summary of Amendments Code of Conduct Edition 16

In the printed draft Edition 16 of the Code, the following key applies to text colour:

Red text= New provisions or explanatory notes

Green text= Text moved from Edition 15 Explanatory Notes to Provisions

Purple text= Text moved from Code Guidelines to Provisions or Explanatory Notes

The following summarises the amendments made in Edition 16 of the Code:

Introduction

- Preamble and Preface merged into one section
- Additional information on:
 - Transparency
 - Promoting high standards
 - Working with others

1. Nature and Availability of Information and Claims

Same section heading as Edition 15

1.2.2 Level of substantiating data

- Additional information on the use and qualification of claims based on surrogate and pre-specified secondary endpoints

1.3 False and misleading claims

- All claims must be referenced – type size 1.5mm
- Position and size of qualifying statement: must appear directly below or adjacent to the claim using a type size not less than 3 mm based on the lower case ‘e’ for printed materials.

2. Promotional material directed at healthcare professionals

Section 2 was previously Types of Product Information – in Edition 16 that information is now found in Section 3

- Note type size changes for reference to the PI if not included in an advertisement; reference to a change of clinical significance; qualifying statements – all are increased to 3mm on lower case ‘e’.
- Divided into types of promotional material
 - 2.1 Print media
 - 2.2 Audiovisual media
 - 2.3 Restricted access television
 - 2.4 Internet – addition of explicit reference to social media and e-newsletters
 - 2.5 Prescribing software
 - Prohibition of advertising prescription medicines

- Companies may pay for the inclusion of medical education for healthcare professionals or patient aids, support program registration and materials in a prescribing software package.
- 2.6 Brand name reminders
 - Restricted to items that are directly relevant to the practice of medicine or pharmacy (no product branded pens, notepads, kitchen items, items which can be attached to a computer such as rechargers, power boards, USB hubs etc)
 - Limit remains at \$20
 - Medical education and items directly relevant to the practice of medicine and pharmacy > \$20 can be corporate branded
 - Corporate branded pens and note pads may be provided to delegates at educational events
- 2.7 Competitions
- 2.8 Communication with the healthcare professional media (new section)
 - Media releases to the professional media
 - Sponsorship of healthcare professional journalists

3. Types of Product Information

Previously Section 2 in Edition 15

- Note changes to type size for some representations of the product information – to make all forms of product information when included in the body of an advertisement 1.5mm, which is the same as the requirement for the Minimum PI.

4. Educational Material directed at Healthcare Professionals

New section heading but information previously in Sections 10.4 and 10.5 in Edition 15

- 4.1 Medical Educational material

Includes reference to education provided via any media – print, internet, social media
- 4.2 Medical literature and reprints
 - Includes reference to medical literature provided via any media – print, internet, social media
 - No part of the reprint or article should be specifically highlighted to draw the attention of the healthcare professional.

5. Company Representatives - Roles and ethical conduct

Previous Section 4 Company Representatives has been divided into 2 sections in Edition 16 – under a heading Company Representatives

- Section 5.3 Inclusion of the recommendation that compliance with the Code form part of the overall performance assessment of company representatives

6. Company Representatives - Training

- Includes new provision requiring regular training to ensure sufficient knowledge to comply with Australian Privacy legislation and Trade Practices legislation to the extent it is relevant to their roles.

7. Product Starter Packs

Previously Section 5.1 in Edition 15 – no significant amendments

8. Product Familiarisation Programs

Previously Section 5.2 in Edition 15 – no significant amendments

- 8.3 minor amendment– change to ‘must’ involve patients with approved indications

Relationship with healthcare professionals

Sections 6, 7 and 10 merged in one new section 9

Includes:

- 9.3 Educational events (general provisions)
- 9.4 Company educational events held in Australia
 - Educational content
 - Venue selection
 - Meals and beverages/hospitality
 - Partner/Family costs
 - Travel
 - Accommodation
 - Entertainment
 - Remuneration
 - Partners, family or guests
 - Provisions of company-branded items
- 9.5 Sponsored educational events (with equivalent subsections to 9.4)
- 9.6 Trade displays
- 9.7 Sponsorship of individual HCPs to attend educational events
- 9.8 Consulting arrangements with HCPs
- 9.9 Advisory Boards
- 9.10 company sponsored medical practice activities
- 9.11 Grants and financial support
- 9.12 Gifts and offers
- 9.13 Discredit to the industry – Previously Section 10.8, but no amendment to provision

Research

- Includes new provisions:
 - Recognising that the conduct of clinical research is governed by legislation and guidelines independent of the Code.
 - The Sections of the Code of Conduct that describe the appropriate interactions between a company and healthcare professionals providing consulting services also apply to interactions that occur when conducting clinical research. Any remuneration for services rendered

should not exceed that which is commensurate with the services supplied. A company may provide reasonable travel, accommodation or hospitality to clinical research personnel engaged in conducting research. Interactions between companies and these clinical research personnel must not include entertainment. A company must not subsidise or pay for the travel, hospitality, accommodation or other expenses for any guest, family, companions or other persons associated with the research.

- Companies must ensure that the requirements of Australia's Privacy Legislation are complied with during any research activity and that all research is undertaken by suitably qualified and experienced individuals or organisations.

10. Post Marketing Surveillance Studies

Previously Section 5.1 in Edition 15

- Minor changes, such as 'should' to 'must' in section 10.1

11. Market research with HCPs

Previously Section 5.2 in Edition 15 - minor changes

- This section specifically relates to market research with HCPs. There is a new section on market research with the general public (Section 12.10)

12 Relationship with the general public

This Section was previously Section 9 in Edition 15. It has been expanded, particularly to explicitly cover all forms of media, including social media and new Sections on Disease Education Activities, access to trade displays and market research with the general public have been included.

- 12.4 Product Specific Media Statements
Section expanded and rearranged to assist companies. It includes subsections on what a product specific media release must include, may also include and must not include.
- 12.7 Disease Education Activities (new section)
- 12.9 Social media (new section)
Explicit that promotion to the general public via such media is prohibited.
- 12.10 Market research with the general public (new section)

13 Relationship with HCOs and patients

This section was Sections 9.5, 9.7, 9.8 and 9.9 in Edition 15. It has been expanded and includes new requirements:

- No company can request to be the sole funder of a HCO or its major programs (13.1)
- Each company must publish on its website a list of HCOs it financially supports or to which it provides significant indirect/non-financial support. The list must describe the nature of the support (but no requirement for monetary value of the support). List must be updated annually. (13.4)

14 Sponsorship of patients or HCO representatives to attend educational events

New section

15. Access to pharmaceutical company trade displays at third party conferences

Information currently in the Edition 15 Guidelines moved to the Code as provisions.

16. Materials for use with patients (patient aids)

Was Section 9.7 in Edition 15 of the Code, with minor amendments.

17 Patient Support Programs

Was Section 9.8 in Edition 15 of the Code.

- Inclusion of reference to the definitions of 'promotion', 'promotional' and 'promotional claim'. Other minor amendments.

18. Discredit to the industry

Previously Section 9.10 – no amendments.

19 – 35 Administration of the Code

Previously Sections 11 - 16 in Edition 15.

- Changed reference to 'minutes' of a Committee to 'the decisions and reasons for the decisions'.
- Included the capacity for the Code Committee, Appeals Committee and Monitoring Committee to include a second consumer member where a complaint under consideration (or materials under consideration in respect of the Monitoring Committee) concerns conduct or material directed at the general public or patients.
- TGA member of the Code Committee reverted to observer status.
- Company representation on Code Committee remains at five, with two Managing Directors, two Medical/Scientific Directors one Marketing Director.
- Company representation on Appeals Committee remains at three, with one Managing Director/Chief Executive, one Medical/Scientific Director and one Marketing Director
- Section 23 Abuse of the Code amended to make it clear that a company against which an allegation of abuse of the Code will have the opportunity to respond to the allegation before the Code Committee considers it. The allegation will only be referred to a company if the Code Committee forms the view that a complaint might be considered frivolous or vexatious (in most cases such allegations are dismissed by the Committee).
- Section 24 Sanctions:
 - Addition of the discretion to refer a failure to undertake cessation or withdrawal of activity or materials to TGA or ACCC
 - Similar discretion for failure to undertake corrective action

- Monetary fines increased to max \$250,000 as follows:

Breach	Fine
Technical	Max \$100,000 (currently \$100,000)
Minor	Max \$100,000 (currently \$100,000)
Moderate	Max \$150,000 (currently \$100,000)
Severe	Max \$200,000 (currently \$100,000)
Severe breach where activities have been completed and no opportunity for correction	Max \$250,000 (currently \$200,000)
Repeat of a previous breach	Max \$250,000 (currently \$200,000)
Failure to complete corrective action in 30 calendar days	Max \$50,000 (currently \$50,000)
Failure to pay a fine in 30 calendar days (new)	Max \$50,000
Abuse of the Code	Max \$200,000 (currently \$200,000)
Cumulative fines for each identified breach within a complaint	Max for any 1 complaint \$300,000

- Appeal bond retained at \$20,000 but the Appeals Committee may refund up to 100% of the bond if appeal is fully successful.
- Educational Event reporting (Section 35.4) – provisions retained in the Code pending further discussion by the Board. However, the reporting period has been amended to April to September and October to March, with 30 calendar days to submit the reports to Medicines Australia. Medicines Australia still required to publish the reports within 3 months of the end of each reporting period.

Appendix 1 Guidelines for Complaints

- Revised content and timeframe table included. No substantial changes to requirements.
- Further timelines for post-intercompany meeting period in which to resolve the issues or submit a complaint.
- Limitation of 24 months from the time an activity occurred or promotional material used in which to submit a complaint.

Appendix 2 Medicines Australia Constitution

- Addition of Section 4.4 (5) of the Medicines Australia Constitution

Appendix 3 Educational Event Report Format

- No amendments

Glossary

- Amendment of definitions of 'Advertisement' to be consistent with Therapeutic Goods Act 1989
- Addition of definition of HCO

- Amendment of definition of 'medical claim' to be consistent with definition of 'therapeutic use' in the Therapeutic Goods Act 1989
- Addition of definition of 'senior executive office' from MA Constitution