Detailed Summary of Amendments
Code of Conduct Edition 17

The following summarises the amendments made in Edition 17 of the Code. This summary does not include every individual amendment. Reference should be made to the Final Draft of Edition 17 of the Code with marked up amendments.

Format of Edition 17

To simplify the format of the Code, Explanatory Notes will no longer be included. The Explanatory Notes that were included in Edition 16 have either been moved into their relevant Sections of the Code of Conduct or removed. Those that have been removed will be included in the Code of Conduct Guidelines which accompanies the Code of Conduct.

Introduction

- Inclusion of high level principles for ethical conduct, developed by the Australian Working Group on Promotion of Therapeutic Goods and the IFPMA for its Code of Marketing Practices 2012
- Reference to APEC 'Mexico Principles' also included
- References to (former) Trade Practices Act and therapeutic goods legislation updated

1. Nature and Availability of Information and Claims

1.2.2 Level of substantiating data

- Additional information on the use of meta-analyses and systematic reviews
- Revision of requirements regarding post-hoc analyses, emphasising that it should be clear to a reader if primary end points are not me or if claims are based on post hoc analyses.

1.4 Unapproved Products and Indications

- This section moved to form a separate section rather than as a sub-section of 1.3 False and misleading claims
- Clarification that prohibition on promotion relates to both unapproved products and unapproved indications
- Additional information included regarding communication about unapproved products/indications at conferences and educational meetings – what is expected of companies in relation to their responsibilities for healthcare professional speakers

1.7 New Products

- Clarification on the acceptable use of the word "new" in promotional materials

1.8 Comparative statements

- Addition of a requirement that if a study is used that does not state a p-value, the lack of a p-value must be explicitly stated in promotional material.

2. Promotional material directed at healthcare professionals

- Removal of any reference to an Abridged PI – only an approved PI and a Minimum PI are required by any provision of Code Edition 17.

2.1.1.1 Primary advertisements and 2.1.1.2 Secondary advertisements

- Removed requirement for PBS dispensed price to be included in advertisements.
- Allowance for Primary and Secondary advertisements to include a reference to a URL where the approved Product Information may be located rather than solely a reference to where it appears in the publication
- Allowance for a Primary advertisement to include a reference to a company 1800 number for the healthcare professional to request a copy of the PI.

2.1.1.3 Short advertisements

- Allowance for Short advertisements to include a reference to a URL where the approved Product Information may be located

2.1.2 Printed promotional material

- Similar requirements regarding inclusion of a reference to a URL or a 1800 number for access to the approved PI.

2.1.4 and 2.1.2 Printed promotional material

- A new requirement for these materials to include a date that the material was prepared or last revised.

2.2, 2.3 and 2.5 Electronic media that includes advertising

- A new requirement for advertisements in electronic media to include a date that the material was prepared or last revised.

2.6 Brand name reminders

- Brand Name Reminders no longer permitted
- Medical and educational items that enhance patient care may be provided, but must not be product branded – (examples are anatomical models and educational literature)
- May provide unbranded pens and notepads at an educational forum, or items that are company branded in accordance with Section 9.4.9.
- Reference to brand name reminders deleted from all relevant sections of the Code (e.g. 9.13 Gifts and Offers and 9.6 Trade Displays)

2.7 Competitions

- Giving of prizes in association with competitions or quizzes no longer permitted
- Companies may offer a quiz to healthcare professionals at a trade display, but no prize may be offered or given.
- Reference to competition prizes removed from Section 9.6 Trade displays

3. Types of Product Information

Removal of any reference to an Abridged PI – only an approved PI and a Minimum PI are required by any provision of Code Edition 17.

- Primary advertisements and printed promotional material must include the Minimum PI, consistent with Code edition 16
- Allowance for providing the approved PI (in first 24 months of advertising) or Minimum PI in hard copy, access via a URL to a website or request via a 1800 number
- Single type size for Product Information of 1mm (hard copy and when included in an advertisement or printed promotional material) **Note**: **Minimum** Product Information in advertisements and printed materials remains at 1.5mm.

3.2 Minimum Product Information

- Addition of dosage and method of use to content of Min PI
- Allowance that if there are multiple indications for a product, the Minimum PI may include only that information relevant to the indication being promoted.
- Boxed warnings must be included in all versions of the Minimum PI, regardless of indication being promoted.

3.3 Changes of clinical significance

- Clarification as when changes of clinical significance are to be communicated to healthcare professionals and how this may be communicated.

4. Educational Material directed at Healthcare Professionals

- No changes proposed

5. Company Representatives - Roles and ethical conduct

5.8 Roles and Ethical Conduct

- Removal of reference to Abridged PI and replaced by reference to Minimum PI

6. Company Representatives - Training

- Includes reference to 'field based medical personnel' to require that such personnel are undertaking or have completed the Code of Conduct component of the Medicines Australia education program and must undertake ongoing training on Privacy legislation and Competition and Consumer legislation as relevant to their role
- Requires that P/T and contracted medical representatives are required to enrol in and progress through the Continuing Education Program within the equivalent of two years of permanent employment.

7. Product Starter Packs

- Include reference to the Council of Australian Therapeutic Advisory Group (CATAG) *Guiding Principles for Medication Access Programs in Australian Public Hospitals*

8. Product Familiarisation Programs

- Clarification that PFP may be initiated at any time. Only one PFP may be conducted for a particular indication. In addition, only 10 patients may be enrolled in a PFP by each participating doctor.
- Clarification that ONLY starter packs may be supplied under a PFP – no trade packs (prohibited by State legislation)
- Updated reference to ACSOM (formerly ADRAC)
- Additional reference to awareness of hospital and institutional requirements for distribution of products under a PFP, and reference to CATAG Guidelines.
- Clarification that cannot conduct a PFP with a S8 medicine due to State and Territory requirements.

Relationship with healthcare professionals

9.10 – Reporting payments to healthcare professional Consultants and Advisory Board members; Speakers fees to be included in educational event reports

- New requirements for reporting of payments to healthcare professional consultants and Advisory Board members
    - to be prepared in two tables (one for Advisory Boards and one for consultants) which are submitted to Medicines Australia.

  - Advisory Boards report (see Appendix 4) must be submitted to Medicines Australia on a 6 monthly basis (the same time frame as educational event reports) to be published on the Medicines Australia website
  - Consultancies report (see Appendix 5) must be submitted to Medicines Australia annually from March 2014 (for 2013 year) to be published on the Medicines Australia website
  - Reports to include honoraria, sitting fees, hospitality, travel, accommodation
- Speakers fees and costs for educational events to be included in 6 monthly educational event reports (see 37.4). Reporting requirement relates to activities from 1 January 2013 (when Code 17 effective). Same timing for submission to Medicines Australia and publication as educational event reports (ie first report required by 30 April 2013, covering 1 January 2013 – 31 March 2013)
- NO NAMES required for any Report relating to transparency of relationships between industry and healthcare professionals.
- Consultancy reporting does NOT include clinical research

<u>9.13 – Gifts and Offers</u>
- Deletion of reference to Brand Name Reminders and Competition prizes
- Explicit statement that it is not appropriate for a company representative to provide flowers, chocolates etc to a healthcare professional.

Research
- Reference to IFPMA *Joint Position on the disclosure of clinical trial information via Clinical Trial registries and databases (2009)*

10. Post Marketing Surveillance Studies
- No changes other than to update ADRAC to ASCOM

11. Ghost writing
- Inclusion of a new provision which defines ghost writing and references the IFPMA Position Paper on publication of clinical trial results, which requires transparency of authorship of clinical papers.

12. Market research with HCPs (renumbered to accommodate Ghost writing)
- Addition of specific prohibition on using market research to promote unapproved products or indications
- Requirement that it must be clear that the market research is being conducted on behalf of a pharmaceutical company, but company not required to be named.
- Requirement that if market research is conducted with consultants who are known to companies by name, any payments must be declared as part of the declaration of payments to consultants and advisory board members.

13 Relationship with the general public (renumbered)

<u>13.1 General Principles</u>
- Explicit that CMI and PI are credible and non-promotional documents that may be made available to the general public

<u>13.4 Relationship with the consumer media (new)</u>
- New statement that makes explicit that companies are responsible to ensure all interactions with consumer media are consistent with the Code and do not constitute promotion of prescription products to the general public

13.4.1 Product Specific Media Statements (renumbered)

- New provision requiring companies to fully brief independent spokespeople on the requirements of the Code and in particular the prohibition on direct to consumer advertising.

13.9 Social media (renumbered)

- Inclusion of principles for companies to engage in the social media

13.10 Market research with the general public (renumbered)

- New requirement that it must be clear that the market research is being conducted on behalf of a pharmaceutical company, but company not required to be named.

14 Relationship with HCOs and patients (renumbered)

- 14.4 - Transparency provision – expansion of the reporting requirement to include the monetary value of financial support of a HCO, including non-financial support
- Reporting to cover the **2013** financial year and to be reported to Medicines Australia by 30 April 2014. Medicines Australia to publish a compiled report on its website.

15 Sponsorship of patients or HCO representatives to attend educational events (renumbered)

- No changes.

16. Access to pharmaceutical company trade displays at third party conferences (renumbered)

- No changes.

17. Materials for use with patients (patient aids) (renumbered)

- Minor amendments.

18. Patient Support Programs (renumbered)

- Inclusion of a definition of a Patient Support Program that expresses the principles underpinning these programs
- Changed ‘should’ and ‘may’ to ‘must’
- Clarification on the insertion of Patient Support Program information in the product package not requiring TGA approval, however must contain a statement that the PSP is not authorised or approved by the TGA.
- New requirement to disclose any payment being made to a healthcare professional, and the amount of the payment, to a patient before they enrol in the program
- New requirement that information provided to patients as part of a PSP must include current, accurate and balanced information about potential risks of the medicine
- New requirement to provide the CMI prior to enrolment or must be given as one of the first documents provided to patients as part of a PSP.

19. Access to Dispensary Data (new)

- New requirement to ensure that company personnel may not access or obtain dispensary data without the informed agreement of the responsible registered pharmacist.
- Data gathered must not include any personal information about patients or healthcare professionals

20. Discredit to the industry (renumbered)

- No changes

21 – 37 Administration of the Code

- Code Committee and Appeals Committee membership expanded to include one pharmacist representative, if a complaint relates to an activity or material directed to the practice of pharmacy.
- Panel of Chairs to be up to 5 suitably qualified lawyers for the Code Committee and up to 3 suitably qualified consultants with industry experience for the Monitoring Committee.
- Include the ability to invite an observer to attend the Monitoring Committee meetings
- Establish a quorum for the Monitoring Committee, being 3 full members, one of which must be a Medicines Australia member representative and one a consumer representative.

Section 35.4 Educational Event reporting

- Educational event reporting to include details of sponsorships of individual healthcare professionals to attend educational events.
- Details to be included in the 6 monthly educational event reports
- Includes registration fees, hospitality accommodation and travel
- Includes the number of people sponsored but does not require the names of people to be disclosed.
- Requires the total amount paid for sponsorship to each educational event.
- Specifically requires speakers fees and costs (travel, accommodation, hospitality) to be included; no names required to be disclosed
- Timing of reporting not amended
- First report in which this information must be disclosed includes the period 1 January 2013 to 31 March 2013, which must be submitted to Medicines Australia by 30 April 2013 for publication by 30 June 2013

Appendix 1 Guidelines for Complaints

- No changes.

Appendix 2 Medicines Australia Constitution

- No changes

Appendix 3 Educational Event Report Format

- Updated to reflect additional reporting requirements regarding sponsorships and speakers (Educational event reporting)

Glossary

- Updating of definition of ADRAC to ACSOM (Advisory Committee on the Safety of Medicines)
- Amendment of the definition of healthcare professional to include those who dispense, recommend a Product (to encompass all relevant registered healthcare professionals, such as nurse practitioners and allied health professionals who may recommend or supply a Product covered by the Code)
- Inclusion of a definition of Personal Information, being the same as that in the Commonwealth Privacy Act 1988
- Reordering of some definitions to correct alphabetical order (Social media, Starter Pack and Substantiation) but no change to the content of these definitions

- Amendment of the definition of Product Familiarisation Program to reflect the changes made to Section 8.