MEDICINES Australia

UTAS
FACULTY OF HEALTH SCIENCE
School of Pharmacy

Code of Conduct Refresher Course

Acknowledgements:

For curriculum design and development:

Ms Sophie Hibburd
Ms Deborah Monk

This education program is developed and delivered for Medicines Australia by UTAS.

Fourth edition January 2013

Contents

Code of Conduct Refresher: Orientation

Overview

Learning goals

- Be familiar with changes to the Code of Conduct in Edition 17
- Be able to apply changes to the Code of Conduct to your role
- Extend your existing knowledge of the Code of Conduct

Introduction

Welcome to the Medicines Australia Code of Conduct Refresher course. Before you begin, ensure you have your copy of the Medicines Australia Code of Conduct Edition 17, and the Medicines Australia Code of Conduct Guidelines for edition 17 (version 2), as the units in this refresher will refer to those documents. All Medicines Australia publications, including a copy of the Code of Conduct Edition 17 in PDF, are available at:

www.medicinesaustralia.com.au

You should also be aware that Code Edition 17 is about to be available as an App, so you can read both the Code and the Code Guidelines on a tablet device.

This refresher course is available in online and print formats, and is designed to be self-directed, so you can work at your own pace. It should take you approximately two hours to complete. There are four units in this refresher, and each unit also contains a summary of the main points where Edition 17 of the Code of Conduct differs from Edition 16. We will summarise the key points of the relevant sections of the Code, and finish each unit with a short quiz to help you check your understanding and give you an opportunity to reflect on how these changes apply to your work.

Student Assistance

For help with online access or administration issues contact the Help Desk on 1300 305 228

Medicines Australia Code of Conduct – Promotional Materials [MA-1B-REF]

Update on Code of Conduct changes

This section is designed to update your knowledge of the key changes to the following sections of the Medicines Australia Code of Conduct Edition 17:

- **Introduction**
- **Section 1 – Nature and availability of information and claims**
- **Section 2 – Promotional material directed at healthcare professionals**
- **Section 3 – Types of Product Information for inclusion with promotional material directed at healthcare professionals**
- **Section 4 – Educational material directed at healthcare professionals**

Introduction

The Code of Conduct is a comprehensive and detailed document that sets the standards required for the promotion of prescription products in Australia. It also embodies and reflects what is often referred to as the 'spirit' of the Code.

The 'spirit' of the Code is simply the ethical principles or standards that the Code seeks to promote. In order to describe these higher order ethical standards, Guiding Principles for ethical conduct by the pharmaceutical industry have been developed and agreed. In Edition 17 ethical principles that were developed by the (Australian) Working Group on the Promotion of Therapeutic Products and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) have been included.

These Principles are stated in the **Introduction** to the Code - in the first section of the Introduction and in principles a) through h). The IFPMA Ethical Principles were developed by the Code Communication Network, which is a group of people from industry Associations and companies around the world who work to promote ethical conduct in the industry.

Participants in the Code Communication Network also participated in an APEC Working Group that developed *Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector (2011)*. These Principles are referenced in the Code Introduction. The Medicines Australia Code is consistent with these Principles.

When you are planning an activity or designing materials for use with consumers or healthcare professionals, consider both the Guiding Principles for ethical conduct as well as the specific requirements in the Code.

Other changes in the Introduction of the Code were to update the title of the former Trade Practices Act to the new Competition and Consumer Act 2010 and update relevant hyperlinks.

Section 1 – Nature and availability of information and claims

Section 1 of the Code of Conduct contains some of the most important standards with which you and your company must comply. You should be aware that it is in these provisions that the majority of breaches of the Code are found. Hence, it is important for you and your colleagues to become familiar with these provisions.

Section 1.4 'Unapproved Products and Indications' has been created as a separate Section in Edition 17 (previously Section 1.3.1).

1.2 Level of Substantiating Data
The principle supporting Section 1.2 is that the basis for any claims must be clear and transparent to a healthcare professional reading any promotional material or advertisement.

Section 1.2.2 has been expanded in Edition 17 to make it clear that certain types of analyses, which might not be obvious otherwise, are clear to a reader so they can properly interpret the information and claims. All claims must be referenced (Section 1.3).

In addition, it must be clear to a reader if:

- a claim is based on a study where the primary end point(s) were not met; and/or
- a claim is referenced to pre-specified secondary end-points where the primary end-points are not met (this was in Edition 16); and/or
- a claim is based on *post-hoc* analyses, and in particular where these analyses are inconsistent with the study's primary endpoints.

Wherever a *post hoc* analysis is used to support a claim, it must be used in the context of the primary endpoints and appropriately qualified.

Section 1.2.2 also refers to use of meta-analyses and systematic reviews. The emphasis here is that companies should not selectively use positive results from these analyses and ignore or minimise negative results.

1.3 False or misleading claims

All claims must be referenced and type size for the reference citation must be not less than 1.5 mm (this is the same as Edition 16).

Edition 17 clarifies that when linking a qualifying statement with a medical or promotional claim, a readily identifiable asterisk or similar device should be used. Qualifying statements must appear directly below or adjacent to the claim using type size not less than 3 mm.

The extensive Explanatory Notes to Section 1.3 (in Edition 16) have been moved to the Code Guidelines. Those retained as provisions in Code Edition 17 are:

- It is unreasonable to cite the results of an excessively favourable (or excessively unfavourable to a comparator product) study in a manner that misleadingly suggests that those results are typical.
- Use of information or conclusions from a study that is clearly inadequate in design, scope or conduct to furnish support for such information and conclusions is not acceptable.
- Data previously valid but made obsolete or false by the evaluation of new data should not be cited.
- Animal or laboratory data should not be used as the sole evidence to support a promotional claim. If animal or laboratory data are used, a prominent statement identifying this type of data and acknowledging that such data do not necessarily predict clinical effects must appear directly below or adjacent to the claim/s using a type size not less than 3 mm based on the font's lower case 'e' for printed materials. The original statement and the qualifying statement must be linked by use of a readily identifiable asterisk or a similar device.

1.4 Unapproved products and Indications

Section 1.3.1 in Edition 16 has been made a separate Section 1.4 in Edition 17.

This provision emphasises that unapproved products or indications must not be promoted to healthcare professionals. A product or indication is considered "approved" for registration when a company has been advised that the product has been entered on the Australian register of Therapeutic Goods and the Product Information (including the approved indications) has been finalised.

Section 1.4 of the Code describes the limited circumstances in which information about unapproved products or indications can be communicated to healthcare professionals in response to an unsolicited request. The medical department or field based medical personnel may provide information on unapproved products or indications in response to an unsolicited request.

This Section also imposes responsibilities on companies to brief healthcare professionals who they invite to speak at an educational meeting on these requirements. Companies must be able to produce documentary evidence of this briefing and its contents which can be publicly disclosed if required.

The requirement to brief speakers applies whether or not the company has provided the healthcare professional with a presentation or other material. It does not apply to independent third party educational events or company-sponsored educational events where an independent scientific faculty has chosen the topics and speakers.

At International Congresses and Australasian Congresses held in Australia, if a product is registered in a country from which a significant number of attendees originate, but the product is not approved in Australia, educational and promotional information about the unapproved product may be made available. In addition, if a product is approved in Australia, with an unapproved indication, the TGA approved Product Information must be readily available at the Congress.

1.6 Unqualified superlatives

The main change to Section 1.6 is the inclusion of the Explanatory Notes into the provisions. There is now a specific prohibition on using the word 'unique' without qualification.

Section 2 - Promotional material directed at healthcare professionals

The most significant changes to section 2 of the Code in Edition 17 are:

- prohibition of the supply of items formerly known as Brand Name Reminders
- prohibition of the supply of competition prizes (irrespective of the value of the prize)
- measures to give greater transparency in providing access to the full Product Information

These amendments are discussed in more detail below.

2.1 Print media

The requirement for the PBS dispensed price to be included in Primary advertisements (Section 2.1.1.1) has been removed. This recognises that with modern technology such as prescribing software and dispensing software, healthcare professionals are unlikely to seek this information in an advertisement.

2.1.1 Journal advertisements directed at healthcare professionals

The Product Information (PI) must always be easily accessible by healthcare professionals. Advertisements in the print media are required to direct a reader to review the Product Information before prescribing, and identify the where the PI can be located. Recognising the modern technology available to access this information, Edition 17 allows companies to make the (full) Product Information available by including in Primary, Secondary or Short advertisements and Printed Promotional Materials:

- a reference to where the PI is printed in a journal and/or
- a URL where the Product Information can be immediately accessed; and/or
- a telephone number for a company information service from which the PI can be requested. If a paper copy of the PI is requested, this must be sent within 5 working days of the request.

The font size for this reference to the location of the Product Information is 3mm based on the font's lower case 'e'.

You should read the specific requirements for Primary, Secondary and Short advertisements, which are also summarised in Table 1 in the Code.

2.1.2 Printed promotional material provided to/or used for discussion with, health professionals

Note the changes regarding availability of the Product Information described under 2.1.1 above. Equivalent changes have been made to the requirements for printed promotional materials.

Edition 17 requires the date that the material was prepared or last revised to be included on all printed promotional materials - detail aids, leave behinds, promotional leaflets etc - as well as including the date on electronic/audio visual materials such as e-detail aids, Apps etc.

New materials distributed after 1 January 2013, or materials that are revised after this date, must include the date that the material was prepared or last revised.

The format for the date is not specified in the Code, but it must be immediately recognisable as a date and be separate from any job number or code on the item. The date is not required on advertisements, as the date of publication in the journal is evidence of the date that the advertisement was current.

2.1.3 Mailing of printed promotional material to healthcare professionals

Edition 17 no longer requires the Product Information to be sent with mailings. The inclusion of the Minimum Product Information and providing access to the Product Information as part of the requirements for promotional materials (Section 2.1.2) still apply.

2.1.4 Printed promotional material for display purposes only

As noted above, the date that the material was prepared or last revised must be included on all printed promotional materials for display purposes.

2.2 Audiovisual media

As noted above, the date that the material was prepared or last revised must be included in all audiovisual promotional materials.

2.3 Restricted access televisions

The date that the material was prepared or last revised must be included in all advertising materials in restricted access television.

2.4 Internet, social media and eNewsletters:

2.4.1 Company controlled websites for healthcare professionals

Consistent with the amendments to provisions for other promotional materials available via electronic media, advertisements on company-controlled websites must make the PI immediately accessible via a hyperlink or URL.

The date that these advertising materials were prepared or last revised must be included.

2.4.2 Social media

Principles for engaging in the social media have been included in Section 13.9 of Edition 17 of the Code. These principles must be followed when companies are engaging with either consumers or healthcare professionals via social media.

2.6 Brand name reminders

A significant change to the Code in Edition 17 is the prohibition of giving items formerly known as Brand Name Reminders to healthcare professionals.

Items for medical education may be provided, and must bear the name of the company supplying the material, but may not bear the name of a product.

At scientific meetings and conferences companies may provide delegates with inexpensive pens, notebooks, lanyards and tote bags, but these may not bear the name of any medicine or product, but may bear the name of the company providing them.

2.7 Competitions

Another significant change is the prohibition on giving competition prizes under Edition 17 of the Code. Companies may offer a quiz at a trade display, but no prize may be offered. The Code Guidelines note that sponsorship of conferences at which third parties run competitions with prizes are acceptable - one example is a passport activity to encourage delegates to attend trade displays - but a company should not contribute to these prizes.

2.8 Communication with healthcare professional media

2.8.1 Media releases

A minor change has been included in this Section - recognising that a media release to the health professional media can inform about a change to a PBS listing or a new National Immunisation Program listing. Note that the situations where a media release to the health professional media can be issued are not limited to the examples listed in Section 2.8.1.

Note: Figures 2 to 14C in the Code of Conduct Guidelines for Edition 17, which provide examples of different types of advertisements and the location of the various elements of mandatory information, have been updated to illustrate the new requirements of Edition 17. You should review these examples to assist you to become familiar with the updated requirements.

Section 3 – Types of Product Information for inclusion with promotional material directed at healthcare professionals

A substantive change to Section 3 of the Code in Edition 17 is the removal of all reference to the Abridged Product Information. The Code now only requires a Minimum Product Information or a Product Information document.

In removing reference to the Abridged PI, the requirements for the Minimum PI were amended to make these more clear. It was not intended that any Minimum PI document that complied with Edition 16 would need to be revised to comply with Edition 17.

If a product has multiple indications, a Minimum PI may be produced that includes only information relevant to the indication or subset of indications being promoted. However, if the product has a boxed warning this must appear in all versions of the Minimum PI.

Code Edition 17 provides more flexibility for communicating changes of clinical significance made to the PI. Changes of clinical significance may be communicated to healthcare professionals by:

- highlighting the change in all forms of the Product Information for a period of 12 months from the date of change with an asterisk ('*') and linking to a footnote in type size not less than 3 mm as measured by the height of the font's lower case 'e'. The footnote must read: *"Please note change(s) in Product Information"*, and/or
- providing a prominent statement on Product websites, and/or
- sending a Dear Healthcare Professional Letter to relevant healthcare professionals.

A company may decide which mechanism(s) are most appropriate for communication of a change of clinical significance.

The minimum type size for Product Information is 1mm measured on the height of the font's lower case 'e'.

The minimum type size for Minimum Product Information is 1.5mm measured on the height of the font's lower case 'e'.

Section 4 – Educational material directed at healthcare professionals

This section includes educational material provided to healthcare professionals by print, audio visual or electronic media (e.g. websites, posters, podcasts, and anatomical models).

4.1 Medical education material

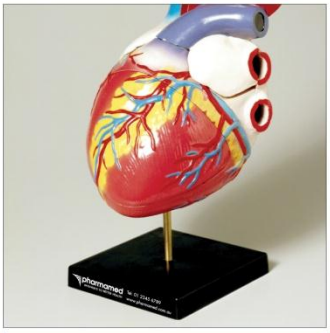
The main update to this Section is the deletion of reference the appearance of a product name on an item for medical education. Brand Name reminders are no longer permitted under Edition 17 of the Code - therefore product brand names may not be applied to items of medical education such as anatomical models or wall charts with anatomical diagrams.

4.2 Medical literature and reprints

The main update to this Section is the incorporation of the previous Explanatory Notes (in Edition 16) into the provisions of the Code.

An item of medical education must include the company name and contact details (city, town or locality of the company) (see Figure 1).

Figure 1



An anotomical model must include the company name and contact details

Promotional Materials – Summary of key learning points

Key learning points:

1. The 'spirit' of the Code is simply the ethical principles or standards that the Code seeks to promote. In order to describe these higher order ethical standards, Guiding Principles for ethical conduct by the pharmaceutical industry have been developed and agreed. These Principles are stated in the **Introduction** to the Code - in the first section of the Introduction and in principles a) through h).

2. It must be clear to a reader if:
   - a claim is based on a study where the primary end point(s) were not met; and/or
   - a claim is referenced to pre-specified secondary end-points where the primary end-points are not met (this was in Edition 16); and/or
   - a claim is based on *post-hoc* analyses, and in particular where these analyses are inconsistent with the study's primary endpoints.

   Wherever a *post hoc* analysis is used to support a claim, it must be used in the context of the primary endpoints and appropriately qualified. (Section 1.2.2)

3. All claims must be referenced in font size not less than 1.5 mm. When linking a qualifying statement with a medical or promotional claim, a readily identifiable asterisk or similar device should be used. Qualifying statements must appear directly below or adjacent to the claim using type size not less than 3 mm.

4. Section 1.4 of the Code describes the limited circumstances in which information about unapproved products or indications can be communicated to healthcare professionals in response to an unsolicited request. The medical department or field based medical personnel may provide information on unapproved products or indications in response to an unsolicited request.

5. Section 1.4 also imposes responsibilities on companies to brief healthcare professionals who they invite to speak at an educational meeting on these requirements. Companies must be able to produce documentary evidence of this briefing and its contents which can be publicly disclosed if required.

6. Edition 17 allows companies to make the (full) Product Information available by including in Primary, Secondary or Short advertisements and Printed Promotional Materials:
   - a reference to where the PI is printed in a journal and/or
   - a URL where the Product Information can be immediately accessed; and/or
   - a telephone number for a company information service from which the PI can be requested. If a paper copy of the PI is requested, this must be sent within 5 working days of the request.

   The font size for this reference to the location of the Product Information is 3mm based on the font's lower case 'e'.

7. The date that the material was prepared or last revised to be included on all printed promotional materials - detail aids, leave behinds, promotional leaflets etc - as well as including the date on electronic/audio visual materials such as e-detail aids, Apps etc.

8. Items formerly known as Brand Name Reminders may no longer be given to healthcare professionals.

9. Edition 17 of the Code prohibits companies giving competition prizes. Companies may offer a quiz at a trade display, but no prize may be offered.

10. The Abridged Product Information has been removed from Code Edition 17. The Code now only requires a Minimum Product Information or a Product Information document.

11. Changes of clinical significance may be communicated to healthcare professionals by:
    - highlighting the change in all forms of the Product Information for a period of 12 months from the date of change with an asterisk ('*') and linking to a footnote in type size not less than 3 mm as measured by the height of the font's lower case 'e'. The footnote must read: *"Please note change(s) in Product Information"*, and/or
    - providing a prominent statement on Product websites, and/or
    - sending a Dear Healthcare Professional Letter to relevant healthcare professionals.

12. Product brand names may not be applied to items of medical education such as anatomical models or wall charts with anatomical diagrams

Promotional Materials – Quiz

Answer the following five questions:

Question 1. Which of the following is **not** a Guiding Principle that applies to the conduct of pharmaceutical companies?

Select one:

a) Pharmaceutical companies may promote prescription medicines to patients if the laws in that country permit it

b) Pharmaceutical companies are responsible for providing accurate, balanced, and scientifically valid data on products

c) The healthcare and well-being of patients are the first priority for pharmaceutical companies

d) Pharmaceutical companies should adhere to both the spirit and the letter of applicable industry codes

Question 2. Which of the following items is acceptable to be given as a Brand Name Reminder?

a) A pen with a product brand name and the AAN on it

b) An anatomical model, such as a model of the heart

c) Antibacterial handwash

d) Companies may not give healthcare professionals items known as Brand Name Reminders

Question 3. It is not permitted to make a claim based on a *post hoc* analysis of study participants if the primary endpoint/s of the original study were not met.

Choose one answer.

A. True

B. False

Question 4. In which manner may a company make the Product Information available to healthcare professionals from an advertisement? Choose one of the following:

a) A reference to where the PI is printed in a journal

b) A URL where the Product Information may be immediately accessed

c) A telephone number for an information service from which the PI may be requested.

d) All of the above

e) Answers b) and c) only

Question 5. What are companies' obligations in regard to a healthcare professional who is asked to give presentations at company-organised educational meetings for healthcare professionals, in order to avoid promotion of unapproved uses or unapproved products?

a) It is unavoidable that a key opinion leader speaker will discuss off-label uses or unapproved products. The speaker is independent, so the company has no obligations regarding their conduct or what they say in a presentation.

b) The company must brief the speaker on the approved uses for relevant products and make sure the speaker is aware that unapproved products and indications must not be promoted. This briefing must be documented, which can be publicly disclosed if required.

c) The company should review the speaker's presentation and remove any reference to unapproved products or indications

d) The company's Medical Director should explain to the speaker that it is OK to respond to a question from the audience about an unapproved indication or unapproved product. The reason they have been asked to speak is their cutting edge knowledge of emerging trends in medical science.

Medicines Australia Code of Conduct – Conduct of Company representatives and Research [MA-1C-REF]

Update on Code of Conduct changes

This section is designed to update your knowledge on the key changes to the following sections of the Medicines Australia Code of Conduct Edition 17:

Company Representatives

- **Section 5 – Roles and ethical conduct**
- **Section 6 – Training**

Provision of Starter Packs

- **Section 7 – Product Starter Packs**

Product Familiarisation Programs (PFP)

- **Section 8 – Product Familiarisation Programs**

Research

- **Section 10 – Post Marketing Surveillance (PMS) Studies**
- **Section 11 – Ghost writing**
- **Section 12 – Market research with healthcare professionals**

Section 5 - Roles and ethical contact

The main change to this section has been to include the former Explanatory Notes into the provisions of the Code.

Section 5.3 in the Code of Conduct Guidelines has been expanded to include a number of State policies regarding interactions between industry and healthcare professionals employed in public health institutions. You should be aware of these policies and conduct your company business accordingly.

Section 6 - Training

Section 6 has been amended to include reference to "field based medical personnel". This term is intended to cover the various roles filled by medically qualified personnel who directly interact with healthcare professionals in the field but are not marketing or sales representatives. The intent of these changes is to ensure that field based medical personnel are required to have completed the Code of Conduct component of the Medicines Australia Continuing Education Program (CEP).

In recognition that medical representatives are sometimes employed on a part-time or short-term contract basis, Sections 6.4 and 6.5 have been amended to require that part-time or contracted personnel (and full time permanent employees) must enrol in the Code of Conduct component of the CEP within the first six months of employment. If a medical representative is contracted for a period of less than 2 years, they must be able to demonstrate that they are progressing through the continuing education program in a timely manner and have completed it (all programs) within the equivalent of two years permanent employment.

Section 7 - Product Starter Packs

The amendments to Section 7 were to:

- include the former Explanatory Notes into the provisions of the Code
- require companies to be familiar with and comply with the requirements of the Council of Australian Therapeutic Advisory Groups (CATAG) *Guiding Principles for Medication Access Programs in Australian public hospitals*. Distribution of starter packs in hospitals must comply with individual hospital requirements.

Section 8 - Product Familiarisation Programs (PFPs)

In response to comments from consumers at workshops held during the Code Review, several provisions for PFPs were changed from "should" to "must":

- Section 8.2 now states that companies must not offer any reward to healthcare professionals, their families or employees for taking part in PFPs.
- Section 8.4 now states that companies must provide a patient information document, which explains the terms of the PFP, to be given to a patient by their healthcare professional

Companies must make the rationale for a PFP available within 10 working days of receiving a request.

The Code Review Panel agreed to provide some greater flexibility concerning the initiation period for PFPs. Section 8.5 allows that a PFP may be initiated at any time following the approval of the product for registration or the approval of new indications. However, only one PFP may be conducted for a particular indication.

The enrolment period for a PFP remains at six months. However, a company may extend the enrolment period if there is a strong clinical and/or equity rationale for such an extension. The number of patients that a healthcare professional can enrol in a PFP remains at 10 patients.

Section 8.7 has been amended to make it clear that ONLY starter packs may be supplied free of charge under a PFP. No trade packs may be supplied as part of a PFP. This section also now includes a specific prohibition on conducting a PFP for an Schedule 8 medicine.

Section 8.8 has been clarified to state that no personal details of patients or individual patient data may be collected under a PFP.

Other changes to Section 8 were to include the former Explanatory Notes into the provisions and to update 8.10 to require that suspected adverse drug reactions spontaneously reported during a PFP must be reported to the TGA (rather than to ADRAC, or its replacement committee).

Research

In recognition of the global industry's commitment to greater transparency about clinical trials, the Code now references the IFPMA *Joint Position on the disclosure of clinical trial information via Clinical Trial registries and databases (2009)*. As a member of the IFPMA, Medicines Australia adopts its policies and position papers.

Section 10 - Post Marketing Surveillance Studies
No significant changes to this section

Section 11 - Ghost writing
This is a new section, which defines 'ghost writing' - where the contributions of professional medical writes are not identified or acknowledged in a publication, either in the authorship line or other acknowledgement.

The section references the IFPMA Position Paper on publication of clinical trial results, which thereby requires transparency of authorship of clinical papers.

Section 12 - Market Research with Healthcare Professionals
There were a number of changes to market research provisions - both in this section and in the later section dealing with market research with consumers.

Section 12.1 permits market research to be undertaken about an unapproved product or an unapproved indication, but emphasises that market research must not be used as a means to promote unapproved products or indications.

Section 12.2 introduces a new requirement that it must be clear to participants in market research that the research is being conducted on behalf of a pharmaceutical company. Recognising that if the name of a company is disclosed to participants that might bias some types of market research, the name of the company need not be disclosed. However, if there is no risk of such bias, the company's name may ne disclosed if desired.

Section 12.6 is another new requirement, which was included as one element in further transparency measures about relationships between industry and healthcare professionals. If market research is conducted with consultants who are selected by the company to participate in the research, and therefore are known to the company by name, these payments must be declared as part of the declaration of payments to consultants or advisory board members. If the market research is being conducted by a third party consultancy (such as a market research company), where the identity of healthcare professionals participating in market research is not known to the company, the declaration of payment is not required.

Conduct of Company representatives and Research – Summary of key learning points

Key learning points:

1. The training requirements in Section 6 ensure that 'field based medical personnel' are required to have completed the Code of Conduct component of the Medicines Australia Continuing Education Program (CEP). (Section 6)

2. Medical representatives who are employed part-time or on a short term contract basis are still required must enrol in the Code of Conduct component of the CEP within the first six months of employment. If a medical representative is contracted for less than 2 years, they must be able to demonstrate that they are progressing through the continuing education program in a timely manner and have completed all programs within the equivalent of two years permanent employment. (Sections 6.4 and 6.5)

3. Companies must provide a patient information document to be given to patients by healthcare professionals when enrolling in a PFP.

4. Requirements for PFPs:
   - Companies must make the rationale for a PFP available within 10 working days of receiving a request.
   - May be initiated at any time following product approval or approval of new indications, but only one PFP may be conducted for a particular indication
   - Enrolment period of six months (same as Edition 16 of the Code), but may be extended if there is a strong clinical and/or equity rationale
   - No more than 10 patients can be enrolled by an individual healthcare professional (same as Edition 16)
   - ONLY starter packs may be supplied, no trade packs
   - PFPs may not be conducted with Schedule 8 medicines
   - No personal details of patients or individual patient data may be collected

5. New Ghost writing section (section 11) - requiring transparency of authorship of publications for the scientific literature

6. Market research with healthcare professionals:
   - Market research must not be undertaken as a means to promote unapproved products or indications.
   - It must be clear to participants in market research that the research is being conducted on behalf of a pharmaceutical company, but the name of the company need not be disclosed.
   - companies must publicly report on payments to healthcare professional consultants if selected by the company to participate in market research and the identity of the healthcare professional is known to the company. Otherwise, reporting of payments to participants in market research is not required.

Conduct of Company representatives and Research Quiz

Use the following information to answer the four questions below:

Question 1. Which statement regarding PFPs is **FALSE**?

Select one:

a) The enrolment period for a PFP must not exceed 6 months

b) Healthcare representatives can enrol as many patients as they wish in the PFP, so long as they are treating them for approved indications for the product.

c) Doctors cannot receive incentives or rewards for prescribing a product

d) PFPs can be initiated at any time following the first supply of the product approved for registration or approval of a new indication

Question 2. Medicineco Inc is setting up a Product Familiarisation Program (PFP) for its new anti-depressant, Maximood™. Answer the following question regarding the Code of Conduct requirements for PFPs.

How quickly after receiving a request must information about the PFP rationale be made available?

Select one:

a) 3 working days

b) 1 month

c) 10 working days

d) 1 week

Question 3. Trent Dubois is a medical representative working for a company that contracts out sales force personnel to therapeutic goods companies - those that sell over the counter products and devices, as well as those that sell prescription medicines.

Trent has just started working at Pharmpre, a prescription medicine company. His contract is for 6 months. In what time period must Trent complete the endorsed Medicines Australia education program?

Select one:

a) He doesn't have to complete the education program, just keep doing the program whilst he is employed at a prescription medicine company

b) In the equivalent of two years of permanent employment

c) Within two years from enrolment, irrespective of his employment history during that time

d) Within three years from enrolment, irrespective of his employment history during that time

Question 4. Medicineco is holding an Advisory Board meeting concerning its new antidepressant product. The Marketing Director decides to conduct some market research with these key opinion leaders, to test the communication strategy for the product. The Advisory Board members will be paid an additional $50 each for their participation in the market research.

Does Medicineco have to report the payment for this market research activity?

1. Yes

2. No

Medicines Australia Code of Conduct – Relationships [MA-1D-REF]

Update on Code of Conduct changes

This section is designed to update your knowledge of the key changes to the following sections of the Medicines Australia Code of Conduct Edition 16:

- **Section 9 – Relationship with healthcare professionals**
- **Section 13 – Relationship with the general public**
- **Section 14 – Relationship with Health Consumer Organisations (HCOs)**
- **Section 15 – Sponsorship of patients and HCO representatives to attend third party educational events**
- **Section 16 – Access to company trade displays at third party conferences**
- **Section 17 – Materials for use with patients (patient aids)**
- **Section 18 – Patient Support Programs**
- **Section 19 – Access to Dispensary Data**
- **Section 20 – Discredit to and reduction of confidence in the industry**

Section 9 - Relationship with healthcare professionals
There were minimal changes made to the main content of Section 9 - Relationship with healthcare professionals, except for the inclusion of requirements relating to transparency of these relationships through reporting of payments to consultants and Advisory Board members. As with other sections of the Code, many of the former Explanatory Notes have been included as provisions in the Code.

9.10 Reporting payments to healthcare professionals consultants and Advisory Board members

This is a new Section in Edition 17 of the Code. It requires companies to provide two new report tables to Medicines Australia for publication on its website:

- An Advisory Boards report (see also Appendix 4) which must be submitted to Medicines Australia on a **6 monthly** basis (the same time frame as educational event reports)
- A Consultancies report (see also Appendix 5) which must be submitted to Medicines Australia **annually** from March 2014 (for the 2013 year)

The reported payments include all honoraria, sitting fees, hospitality, travel, accommodation paid to healthcare professionals. The report for Advisory Boards is similar to the report for educational events, being a report per Advisory Board meeting. The report for consultancies by healthcare professionals is an aggregate of all fees paid and associated costs and expenses, along with the number of consultancies and the number of consultants involved.

There is **no requirement** to report individual healthcare professional's names in association with these reports.

The Code of Conduct Guidelines provide substantial information and a decision tree to assist companies to determine whether to report particular interactions as a consultancy or an Advisory Board activity.

The first Advisory Board report will cover activities from 11 January 2013, when the Code became effective, to 31 March 2013. This report must be submitted by 30 April 2013 and will be published by Medicines Australia by 30 June 2013.

The first Consultancies report will cover consultancies from 1 January 2013 to 31 December 2013, and must be submitted to medicines Australia by 30 April 2014 for publication by 30 June 2014. The Consultancies report will be submitted annually thereafter.

Section 9.13 - Gifts and offers

This section has been updated to delete reference to competition prizes and brand name reminders, consistent with other amendments to Sections 2.6 and 2.7.

A new provision has been included in this section to explicitly prohibit a company representative from providing flowers, chocolates etc to a healthcare professional. If a company representative has a personal relationship with a healthcare professional beyond their working relationship, which may warrant a gift of this kind, it may be given by the individual entirely at their own expense.

Section 13 - Relationship with the general public

As with other sections of the Code, many of the former Explanatory Notes have been included as provisions in the Code.

13.1 General principles
A new provision has been included which emphasises the importance of making Consumer Medicines Information (CMI) and Product Information (PI) available to members of the general public. The Code recognises that these documents are regarded as non-promotional and should be made available in a non-promotional manner.

13.3 Promotion to the general public
This section was amended to clarify that an unscheduled product which can only be obtained via a healthcare professional may only be promoted to a healthcare professional. This amendment is intended to cover products such as blood products or blood component replacement products, which are regulated as therapeutic goods.

13.4 Relationship with the consumer media
This is a new provision that makes it 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. It also recognises that media organisations are independent from the pharmaceutical industry and are therefore not bound by the Code. Whilst companies may not control the final output by the media, they may be held responsible for their interactions with the consumer media.

13.5 Product specific media releases
A minor change to this provision to include reference to the National Immunisation Program (NIP) and that a new or changed PBS listing or NIP listing is an acceptable reason for issuing a media release to the general media.

13.4.5 Product Specific Media Statements
This is a new provision that requires companies to fully brief independent spokespeople on the requirements of the Code and the Therapeutic Goods legislation and in particular the prohibition on direct to consumer advertising. Companies must be able to produce documentary evidence of this briefing and its content if required.

13.9 Social media
The provisions on social media as an avenue for communication with the general public have been expanded. The Code Review Panel recognised that it is not possible for the Code to cover every type of interaction via social media, particularly as new media and technology are becoming available frequently. The Panel developed three principles, which are:

- Companies are responsible for all content on company-initiated and/or controlled Social Media sites and activities. Content which does not conform to community standards of ethics and good taste or which relates to unapproved products or indications should be promptly removed from the site.
- All Companies should have policies and procedures which describe the roles and responsibility of its employees and contractors when interacting in the social media space to ensure compliance with the Code of Conduct. Any activity on a Social Media site by a Company employee, or the employee of an agency acting on the Company's behalf, must comply with the Code of Conduct.

- Suspected adverse drug reactions noted during monitoring of Social Media sites must be reported to TGA in accordance with the current TGA document *Australian Guideline for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines Regulated by the Drug Safety and Evaluation Branch.*

13.10 Market research with the general public
Consistent with the amendment to Section 12, relating to market research with healthcare professionals, the provision requires that it must be clear to a consumer participant in market research that the research is being conducted on behalf of a pharmaceutical company. Recognising that identifying the company by name might bias the research, the name of the particular pharmaceutical company need not be disclosed.

Section 14 - Relationship with Health Consumer Organisations (HCOs)
There have been two important changes to this section of the Code:

- In addition to the requirement for companies to publish a report about the nature of their relationships with Health Consumer Organisations (HCOs), which was required in Edition 16, this report must now include the monetary value of the financial support provided and any significant non-financial support. This report must be produced annually, with the first report including financial information being for the 2013 calendar year.
- The report about relationships with HCOs must be submitted to Medicines Australia for publication (rather than being published on the company's website). The first report must be submitted to Medicines Australia by 30 April 2014 and annually thereafter.

Companies need to inform the HCOs that they provide financial support or sponsorship to that this information will be publicly disclosed, including the monetary value.

Section 17 - Materials for use with patients (patient aids)
There were minor editorial changes to this section

Section 18 - Patient Support Programs
The consumer workshops conducted as part of the Code Review in 2012 revealed that there was some degree of misunderstanding about the nature of patient support programs and some suspicion that these program lacked legitimacy and were essentially a marketing tool. Consumers were keen to see these provisions strengthened to ensure that they were properly designed and were for the benefit of consumers. They also wanted to ensure there was transparency about any payments received by a healthcare professional in association with these programs.

The following changes were therefore included in the Code provisions:

- A definition of a Patient Support Program that expresses the principles underpinning these programs
- Emphasis that any information provided to consumers as part of a PSP must not be promotional
- 'Should' and 'may' changed to 'must' in several provisions, clarifying that these provisions were not optional
- With the TGA's agreement, companies may include an insert in a product package about the availability of a Patient Support Program. This insert does not require TGA approval, however the insert must state that the PSP is not authorised or approved by the TGA.
- A 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.
- A 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
- A new requirement to provide the CMI prior to enrolment or the CMI must be one of the first documents provided to patients as part of a PSP.

19. Access to Dispensary Data

This is a new requirement which is intended to ensure that company personnel do not access or obtain dispensary data without the informed agreement of the responsible registered pharmacist. Any data obtained from a dispensary software system must not include any personal information about patients or healthcare professionals.

Relationships – Summary of key learning points

Relationship with healthcare professionals:

1. New reporting requirements concerning payments to healthcare professional consultants and Advisory Board members. (Section 9.10)
   - An Advisory Boards report (see also Appendix 4) which must be submitted to Medicines Australia on a **6 monthly** basis (the same time frame as educational event reports)
   - A Consultancies report (see also Appendix 5) which must be submitted to Medicines Australia **annually** from March 2014 (for the 2013 year)

2. Brand Name Reminders and Competition prizes are no longer acceptable as gifts or offers. (Section 9.13)

Relationship with general public:

3. Companies are responsible for ensuring that all their interactions with consumer media are consistent with the Code and do not constitute promotion of prescription products to the general public. (Section 13.4)

4. Companies must fully brief independent spokespeople on the requirements of the Code and Therapeutic Goods legislation and particularly on the prohibition on direct to consumer advertising. Companies must be able to produce documentary evidence of this briefing and its content if required. (Section 13.4.5)

5. New principles for using the social media. (Section 13.9)

6. For market research with consumers, participants must be informed that the research is being conducted on behalf of a pharmaceutical company. (Section 13.10)

Relationship with Health Consumer Organisations (HCOs) and patients:

7. Additional requirements for reporting the monetary value of financial support provided to Health Consumer Organisations. This report must be submitted annually to Medicines Australia for publication on its website (Section 14)

8. The following (main) changes were included in the Code provisions relating to Patient Support Programs (Section 18):
   - Any information provided to consumers as part of a PSP must not be promotional
   - Companies may include an insert in a product package about the availability of a Patient Support Program. This insert does not require TGA approval, however the insert must state that the PSP is not authorised or approved by the TGA.
   - A 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.
   - A 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
   - A new requirement to provide the CMI prior to enrolment or the CMI must be one of the first documents provided to patients as part of a PSP.

Relationships – Quiz

Use the information below to answer the following five questions:

Question 1. Pharmaceutical company Pharmpre has established several Advisory Boards associated with the different therapeutic specialties with which Phamrpre is involved. The Chairman of one of the Advisory Boards, Professor Greg Smith, has asked the Pharmapre Medical Director to explain what are the new requirements under the Medicines Australia Code of Conduct. Professor Smith has heard that some new reports are required for Advisory Boards.
Which of the following need to be reported in the Advisory Board Report?

Tick/choose all that are correct.

a) Names of Advisory Board members
b) Travel costs for Advisory Board members
c) The number of members of each Advisory Board
d) Venue costs, including room hire and audio-visual equipment
e) Honoraria paid to Advisory Board members

Question 2. Pharmaceutical company Pharmpre works with a variety of healthcare professionals who provide advice and consult to the company. These healthcare professionals' main employment is treating patients, but as they are key opinion leaders and experts in their field, they also provide advice to companies as consultants.

Phamrpre's Managing Director needs to know what is the scope of payments that must be reported in the new Consultancies report under Edition 17 of the Code. What needs to be disclosed?

What is your advice to the Managing Director at Pharmpre?

a) The consulting fees
b) Any hospitality paid for in association with the consultancy provided
c) Any travel costs for the consultant associated with the consulting work
d) Any accommodation costs required for the consultancy
e) Costs for Pharmpre staff time spent working on the project

Question 3. Which of the following is **NOT** a principle stated in the Code for engaging in the social media?

Choose one of the following:

a) It is appropriate and necessary for companies to interact with the general public via social media such as YouTube, Facebook or Twitter. The purpose of this interaction must be to enhance the quality use of medicines and to provide current, accurate and balanced information about prescription products approved for use in Australia.
b) Suspected adverse drug reactions noted during monitoring of Social Media sites must be reported to TGA in accordance with the current TGA document *Australian Guideline for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines Regulated by the Drug Safety and Evaluation Branch.*
c) All Companies should have policies and procedures which describe the roles and responsibility of its employees and contractors when interacting in the social media space to ensure compliance with the Code of Conduct. Any activity on a Social Media site by a Company employee, or the employee of an agency acting on the Company's behalf, must comply with the Code of Conduct.
d) Companies are responsible for all content on company-initiated and/or controlled Social Media sites and activities. Content which does not conform to community standards of ethics and good taste or which relates to unapproved products or indications should be promptly removed from the site.

Question 4. Pharmaceutical company Medicineco has recently achieved registration for a new product to treat Alzheimer's disease. Communications Director Julie Jones intends to issue a media statement and wants to offer media outlets two healthcare professional and one consumer spokespeople for iterview. Julie is unsure of the company's obligations under the Code and speaks to the Compliance Director to get his advice.

Which of the following statements is **most correct** regarding Medicineco's obligations for the spokespeople?

a) As long as the PR agency briefs the speakers, Medicineco has met its obligations
b) Medicineco must ensure that the healthcare professionals and consumer spokespeople are fully briefed on the Code and Therapeutic Goods legislation
c) The healthcare professionals and the consumer are independent from the industry and therefore Medcineco does not have any obligations or responsibilities if they are spokespeople at a media event
d) Medicineco must ensure that the healthcare professionals and consumer spokespeople are fully briefed on the Code and Therapeutic Goods legislation AND that this briefing and its content is documented

Question 5. Pharmpre has recently achieved registration for its new product for the treatment of Alzheimer's disease. Recognising that Alzheimer's disease is a very difficult condition to manage, and often patients who commence therapy already have significant symptoms, Pharmpre decides it will initiate a Patient Support Program for the new product. The company will pay a fee, approximately equivalent to a dispensing fee, to pharmacists in compensation for completing the paperwork and counseling when enrolling patients in the Program.

Which of the following must be included in the arrangements and literature for the Patient Support Program?

Select **one**:

a) The fact that the pharmacist receives a fee, and the amount of the fee must be disclosed in writing to the patient before enrolment
b) The Consumer Medicine Information document must be provided to patients before enrolment or given to them immediately following enrolment
c) Patients must be informed that they can opt out of the program at any time
d) Advice that information about their progress, including test results, will be provided to Pharmpre
e) All of the above
f) Options a), b) and c) only

Medicines Australia Code of Conduct – Administration of the Code [MA-1E-REF]

Update on Code of Conduct changes

This section is designed to update your knowledge of the key changes to the following sections of the Medicines Australia Code of Conduct Edition 16:

- **Sections 21 – 29 Complaints and appeals**
- **Sections 30 – 34 Monitoring**
- **Sections 35 – 37 Reporting and compliance procedures**
- **Appendix 1**
- **Appendix 2**
- **Appendices 3, 4 and 5**
- **Glossary**

The changes to these Sections of the Code were relatively minor in developing Edition 17 of the Code.

Sections 21 – 29 Complaints and appeals

- The Code Committee and Appeals Committee membership has been expanded to include one pharmacist representative, if a complaint under consideration relates to an activity or material directed to the practice of pharmacy
- A small administrative amendment was made to the number of members of the Panel of Chairs of Code, Appeals and Monitoring Committees: to be up to 5 suitably qualified lawyers for the Code and Appeals Committees and up to 3 suitably qualified consultants with industry experience for the Monitoring Committee.
- Code Edition 17 establishes 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.
- In addition, Edition 17 allows the Monitoring Committee to invite an observer to attend Monitoring Committee meetings

Section 20 – Membership of the Code Committee
20.1 Membership
Where a complaint is in relation to an activity or material directed at the general public or patients, a second consumer representative will be appointed. Full membership now includes: two representatives from Medicines Australia and one Medicines Australia Member Marketing Director. Observers now include one representative of the Therapeutic Goods Administration (TGA). Secretariat now includes Medicines Australia officer responsible for the Ethical Conduct Program.

Section 37 - Reporting
37.4 Educational event reports

- The Code has been amended to require educational event reports to include details of sponsorships of individual healthcare professionals to attend any educational event. These details to be included in the established 6 monthly educational event reports. This will include registration fees, hospitality accommodation and travel. The report will have to state the number of people sponsored and the total amount paid to sponsor healthcare professionals to attend educational events but does not require the names of people to be disclosed.
- The Code provisions also now specifically require speakers fees and costs (travel, accommodation, hospitality) to be included in educational event reports; no names of healthcare professionals are required to be disclosed
- The timing of educational event reporting was not amended
- The 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)

Appendices 4 and 5 - new Report Formats for Advisory Board Report and Consultancies Report

- The table for educational events formed the basis for the new Advisory Board reports.
- A high level summary for the consultancies annual report has been included in Appendix 5

Glossary updates

- 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.

Administration of the Code: Summary of key learning points

Key learning points

1. The Code Committee and Appeals Committee will include a pharmacist when a complaint under consideration is directed to pharmacy

2. The Monitoring Committee may invite an observer to attend its meetings

3. All sponsorships of healthcare professionals to attend educational meetings must be included in educational event reports, including the number of people sponsored and the total cost.

4. New Appendices 4 and 5 provide tables for reporting Advisory Board meetings (6 monthly) and Consultancies with healthcare professionals (annually)

There are no Quiz questions for this Section.

Medicines Australia Code of Conduct Edition 17 – Summary of Amendments

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, where still relevant, 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.

9 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 35.4). 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

9.13 – Gifts and Offers

- 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)

13.1 General Principles

- Explicit that CMI and PI are credible and non-promotional documents that may be made available to the general public

13.4 Relationship with the consumer media (new)

- 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

13.4.5 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 – 36 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 37.4 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.

Code of Conduct Refresher Quizzes – Answers

MA-1B-REF Quiz answers:

Question 1. Which of the following is **not** a Guiding Principle that applies to the conduct of pharmaceutical companies?

Answer: Pharmaceutical companies may promote prescription medicines to patients if the laws in that country permit it

Explanation: Refer to Code of Conduct, Edition 17, Introduction. Guiding Principles Items a) to h)

Question 2. Which of the following items is acceptable to be given as a Brand Name Reminder?

Answer: Companies may not give healthcare professionals items known as Brand Name Reminders

Explanation: Refer to Code of Conduct Section 2.6

Question 3. It is not permitted to make a claim based on a *post hoc* analysis of study participants if the primary endpoint/s of the original study were not met.

Answer: False

Explanation: Post hoc analyses may be used as the basis to support claims, but it must be clear to a read that the claim is based on a post hoc analysis and that the primary endpoints of the study were not met. Section 1.2.2 Level of substantiating data.

Question 4. In which manner may a company make the Product Information available to healthcare professionals from an advertisement? Choose one of the following:

Answer: All of the above

Explanation: See Section 2.1.1.1

Question 5. What are companies' obligations in regard to a healthcare professional who is asked to give presentations at company-organised educational meetings for healthcare professionals, in order to avoid promotion of unapproved uses or unapproved products?

Answer:

e) The company must brief the speaker on the approved uses for relevant products and make sure the speaker is aware that unapproved products and indications must not be promoted. This briefing must be documented, which can be publicly disclosed if required.

Explanation: See Section 1.4

MA-1C-REF Quiz answers:

Question 1. Which statement regarding PFPs is **FALSE**?

Answer: Healthcare representatives can enrol as many patients as they wish in the PFP, so long as they are treating them for approved indications for the product.

Explanation: See Section 8.8.

Question 2. Medicineco Inc is setting up a Product Familiarisation Program (PFP) for its new anti-depressant, Maximood™. Answer the following question regarding the Code of Conduct requirements for PFPs.

How quickly after receiving a request must information about the PFP rationale be made available?

Answer: 10 working days

Explanation: See Section 8.1.

Question 3. Trent Dubois is a medical representative working for a company that contracts out sales force personnel to therapeutic goods companies - those that sell over the counter products and devices, as well as those that sell prescription medicines.

Trent has just started working at Pharmpre, a prescription medicine company. His contract is for 6 months. In what time period must Trent complete the endorsed Medicines Australia education program?

Answer: In the equivalent of two years of permanent employment

Explanation: See Section 6.5

Question 4. Medicineco is holding an Advisory Board meeting concerning its new antidepressant product. The Marketing Director decides to conduct some market research with these key opinion leaders, to test the communication strategy for the product. The Advisory Board members will be paid an additional $50 each for their participation in the market research.

Does Medicineco have to report the payment for this market research activity?

Answer: Yes

Explanation: See Section 12.6

MA-1D-REF Quiz answers:

Question 1. Pharmaceutical company Pharmpre has established several Advisory Boards associated with the different therapeutic specialties with which Phamrpre is involved. The Chairman of one of the Advisory Boards, Professor Greg Smith, has asked the Pharmapre Medical Director to explain what are the new requirements under the Medicines Australia Code of Conduct. Professor Smith has heard that some new reports are required for Advisory Boards.
Which of the following need to be reported in the Advisory Board Report?

Tick/choose all that are correct.

Answer: All of the following **EXCEPT:** Names of Advisory Board members

Explanation: See Appendix 4 and Section 9.10

Question 2. Pharmaceutical company Pharmpre works with a variety of healthcare professionals who provide advice and consult to the company. These healthcare professionals' main employment is treating patients, but as they are key opinion leaders and experts in their field, they also provide advice to companies as consultants.

Phamrpre's Managing Director needs to know what is the scope of payments that must be reported in the new Consultancies report under Edition 17 of the Code. What needs to be disclosed?

What is your advice to the Managing Director at Pharmpre?

Answer: All of the following **EXCEPT:** Costs for Pharmpre staff time spent working on the project

Explanation: See Appendix 4 and Section 9.10

Question 3. Which of the following is **NOT** a principle stated in the Code for engaging in the social media?

Answer: This is not a social media principle:
It is appropriate and necessary for companies to interact with the general public via social media such as YouTube, Facebook or Twitter. The purpose of this interaction must be to enhance the quality use of medicines and to provide current, accurate and balanced information about prescription products approved for use in Australia.

Explanation: See Section 13.9

Question 4. Pharmaceutical company Medicineco has recently achieved registration for a new product to treat Alzheimer's disease. Communications Director Julie Jones intends to issue a media statement and wants to offer media outlets two healthcare professional and one consumer spokespeople for iterview. Julie is unsure of the company's obligations under the Code and speaks to the Compliance Director to get his advice.

Which of the following statements is **most correct** regarding Medicineco's obligations for the spokespeople?

Answer: Medicineco must ensure that the healthcare professionals and consumer spokespeople are fully briefed on the Code and Therapeutic Goods legislation **AND** that this briefing and its content is documented

Explanation: See Section 13.4.5

Question 5. Pharmpre has recently achieved registration for its new product for the treatment of Alzheimer's disease. Recognising that Alzheimer's disease is a very difficult condition to manage, and often patients who commence therapy already have significant symptoms, Pharmpre decides it will initiate a Patient Support Program for the new product. The company will pay a fee, approximately equivalent to a dispensing fee, to pharmacists in compensation for completing the paperwork and counseling when enrolling patients in the Program.

Which of the following must be included in the arrangements and literature for the Patient Support Program?

Answer: All of the options EXCEPT: Advice that information about their progress, including test results, will be provided to Pharmpre

Explanation: See Section 18 i)