MEDICINES Australia

CODE OF CONDUCT

EDITION

18

THIS PAGE HAS BEEN INTENTIONALLY LEFT BLANK

CODE OF CONDUCT • EDITION 18

Adopted 17 June 2014

Authorised by ACCC 24 April 2015

Effective 16 May 2015

Amendments adopted 11 June 2015

WHERE TO FIND ASSISTANCE

If you have any questions or enquiries in relation to the Code of Conduct please contact Medicines Australia:

Phone: 02 6122 8500

Email: secretarycodecommittee@medicinesaustralia.com.au

A glossary of terms is provided at page 86.

The *Code of Conduct Guidelines* (*Code Guidelines*) has also been produced as a separate publication that will enhance a reader's understanding and application of the requirements of the Code. The Guidelines should be read in conjunction with the Code of Conduct.

The Code of Conduct and *Code of Conduct Guidelines* are available from Medicines Australia's website at www.medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition.

A free copy of the Code of Conduct can be obtained by phoning Medicines Australia on 02 6122 8500 or by completing the online order form available at http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/.

Medicines Australia

Level 1

16 Napier Close

Deakin ACT 2600

Phone: (02) 6122 8500

Facsimile: (02) 6122 8555

Email: secretarycodecommittee@medicinesaustralia.com.au

Web: www.medicinesaustralia.com.au

ABN 23 126 990 001

Contents

Introduction

The Australian therapeutic products industry promotes the concept of good health incorporating the quality use of therapeutic products which is based on genuine consumer health needs and supported by the ethical conduct of all parties. The quality use of therapeutic products means:

- Selecting diagnostic and treatment options wisely based on the best available evidence and the consumer's needs;
- Choosing suitable therapeutic products if this is considered necessary; and
- Using therapeutic products safely and effectively.

Therapeutic industry codes have as their primary objective the maintenance of the trust and confidence of, and accountability to, all communities with which they engage, the effectiveness of which is assessed through the eyes of the relevant community.

Therapeutic products industry sectors will collaborate with relevant stakeholders in developing their Codes of Conduct, updating these Codes and in ongoing education, monitoring and compliance.

Medicines Australia Code of Conduct (the Code)

Established in 1960, the pharmaceutical industry Code of Conduct sets out standards of conduct for the activities of companies when engaged in the promotion of prescription products used under medical supervision as permitted by Australian legislation. The Code owes its origin to the determination of Medicines Australia to secure universal acceptance and adoption of high standards in the promotion of prescription products for human use.

The Code provides the mechanism for the pharmaceutical industry to establish and maintain an ethical culture through a committed, open and transparent, self-regulatory approach.

The Code should be viewed as the minimum set of standards required to promote prescription products in Australia and does not in any way prohibit more stringent and comprehensive requirements being applied by individual companies.

The Code incorporates the principles set out in the International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA) Code of Pharmaceutical Marketing Practices. This Code can be accessed at: http://www.ifpma.org/ethics/ifpma-code-of-practice/about-ifpma-code-of-practice.html

The following Guiding Principles were developed and incorporated into the 2012 IFPMA Code of Practice and set out the basic standards which apply to the conduct of IFPMA Member Companies, which includes Medicines Australia Members, and their agents.

a) The healthcare and well-being of patients are the first priority for pharmaceutical companies.
b) Pharmaceutical companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities.
c) Pharmaceutical companies' interactions with stakeholders must at all times be ethical, appropriate and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence.
d) Pharmaceutical companies are responsible for providing accurate, balanced, and scientifically valid data on products.
e) Promotion must be ethical, accurate, balanced and must not be misleading. Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use.
f) Pharmaceutical companies will respect the privacy and personal information of patients.
g) All clinical trials and scientific research sponsored or supported by companies will be conducted with the intent to develop knowledge that will benefit patients and advance science and medicine. Pharmaceutical companies are committed to the transparency of industry sponsored clinical trials in patients.
h) Pharmaceutical companies should adhere to both the spirit and the letter of applicable industry codes. To achieve this, pharmaceutical companies will ensure that all relevant personnel are appropriately trained.

In addition, the Code is consistent with the Principles described in the APEC *Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector (2011)*.

The Code complements the legislation requirements of the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990*.

To ensure that the Code continues to reflect current community and professional standards and current government legislation, extensive reviews are conducted on a triennial basis.

It is the responsible role of members of the pharmaceutical industry to provide on-going, objective and scientifically valid interpretations of data on prescription products to healthcare professionals. The industry also has an obligation to provide appropriate non-promotional information on prescription products to members of the general public. The Code provides the standard for the provision of this information.

Promoting Quality Use of Medicines

The *National Strategy for Quality Use of Medicines* (QUM) recognises that many people maintain their health without using medicines, while for others medicines play an important role in maintaining health, preventing illness and curing disease.

The pharmaceutical industry is a partner to Australia's *National Medicines Policy* (NMP), the overall aim of which is to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved. The NMP has four central objectives based on active and respectful partnerships, taking into account elements of social and economic policy.

The National Strategy for QUM and the NMP can be accessed at www.health.gov.au

The NMP objectives are:

- timely access to medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

The industry undertakes:

- to provide medicines that conform to the highest standards of safety, efficacy and quality;
- to ensure that medicines are supported by comprehensive technical and information services in accordance with currently accepted medical and scientific knowledge and experience;
- to use professionalism in dealing with our NMP partners including healthcare professionals, public health officials and consumers; and
- to promote the quality use of medicines and principles within the *National Strategy for Quality Use of Medicines.*

The industry is committed to QUM and rational prescribing, and strongly recommends that its products be used only in accordance with the directions and advice of healthcare professionals. To ensure that information upon which to make informed prescribing decisions is available, it is necessary for companies to disseminate to healthcare professionals the specialised medicine information gained during the research and development process, and from experience gained in clinical use. In doing so, the company draws attention to the existence and nature of a particular product by appropriate educative and promotional measures.

With the full cooperation of the industry, there is adequate legislation designed to safeguard the public by ensuring that all products promoted meet standards of safety, quality and efficacy which are acceptable in light of present knowledge and experience.

While it is possible to legislate satisfactorily for the testing, manufacture and control of products, appropriate standards of promotional conduct cannot be defined by the same means. For this reason, responsible companies have concurred in the promulgation of the Code and submitted to its constraints.

Promoting High Standards

Medicines Australia is committed to continuous and demonstrable improvement in industry conduct associated with engagement with our many stakeholders, and also to achieving enhanced understanding of, and compliance with, the Code. Members of Medicines Australia must abide by the Code in both spirit and letter.

Companies should ensure that all agents acting on their behalf are fully conversant with the Code.

Pharmaceutical companies which are not members of Medicines Australia are encouraged to accept and observe the Code in total in addition to their obligations for product registration under the *Therapeutic Goods Act 1989*.

Transparency and Accountability

The Australian pharmaceutical industry collaborates with healthcare professionals in Australia to deliver up-to-date information about the safe, effective and appropriate use of the medicines they prescribe, dispense, administer or recommend.

The industry also engages healthcare professionals to obtain feedback and learn from their experience in using medicines in a practical setting. This open dialogue is critical in enhancing the quality use of medicines, building shared knowledge and identifying future needs that can be met through research and development.

It is important that the community continues to trust and have confidence in the relationships between pharmaceutical companies and their doctors, pharmacists, nurses and other healthcare professionals. In response to community feedback, Medicines Australia has led the collaboration with healthcare professional organisations and patient groups to develop a strong and pragmatic framework, included in this 18th edition of the Code, that will deliver further transparency around payments and other financial relationships between pharmaceutical companies and individual healthcare professionals.

These new transparency measures are an important step forward for industry, healthcare professionals and, importantly, for Australian patients.

Working With Others

Pharmaceutical companies must always be cognisant of the ethical requirements and codes of practice which apply to healthcare professionals, other professionals and their business associates within the industry.

The Code recognises the relationship between health consumer organisations (HCOs) and pharmaceutical companies and the need for both parties to work together in a transparent and accountable way.

Legislative and Regulatory Requirements

In addition to the Medicines Australia Code of Conduct there are Australian legislative and regulatory requirements. Adherence to the Code in no way reduces a company's responsibilities to comply with the Competition and Consumer Act, Commonwealth and State Therapeutic Goods Acts and other requirements, legislation and Codes.

Competition and Consumer Act 2010

http://www.austlii.edu.au/au/legis/cth/consol_act/caca2010265/

Therapeutic Goods Act 1989 and *Therapeutic Goods Regulations 1990*

www.comlaw.gov.au/comlaw/management.nsf/lookupindexpagesbyid/IP200401372

http://www.comlaw.gov.au/Details/F2011C00381

Privacy Act 1988 (Cth)

http://www.comlaw.gov.au/Series/C2004A03712

Code Administration

The Constitution of Medicines Australia Limited provides that each Member Company must conform to and be bound by both the Constitution and the Code of Conduct.

Medicines Australia is responsible for the provision of advice and training on the Code; provides the Secretariat for all Code Committees; is responsible for the administration of complaints, the publication of the outcomes from complaint determinations and the compilation of statistics related to the complaints process.

Complaints

The pharmaceutical industry is committed to having in place consistent, transparent, fair and robust mechanisms for receiving and investigating complaints.

How to Lodge a Complaint

If you are considering lodging a Code of Conduct complaint, but are unsure of how to go about it, please contact Medicines Australia for assistance:

Phone: 02 6122 8500

Email: secretarycodecommittee@medicinesaustralia.com.au

Guidelines for lodging a complaint and a 'Complaints Submission Form' for non-industry Complainants are also available on the Medicines Australia website at www.medicinesaustralia.com.au.

Complaints received by Medicines Australia are considered by the Code of Conduct Committee and, when required, by the Appeals Committee. The permanent members of all Code Committees are independent of Medicines Australia. The members of these Committees bring extensive experience in Competition and Consumer law, public health, general practice, specialist medicine, consumer advocacy and evaluation of the utility of products in a variety of research and clinical situations.

Neither the Medicines Australia Board nor staff determine complaints.

The determinations made by the Code and Appeals Committees are published in quarterly and annual reports on the Medicines Australia website. Membership of the Committees and Code Reports can be found on the Medicines Australia website at www.medicinesaustralia.com.au.

Educational and Promotional Material Directed at Healthcare Professionals

1. Nature and Availability of Information and Claims

1.1 Responsibility

It is the responsibility of companies, their employees and advisers to ensure that the content of all promotional and medical claims is balanced, accurate, correct, fully supported by the Product Information, literature or 'data on file' or appropriate industry source, where these do not conflict with the Product Information. It is fundamental that any claim made must be consistent with the Australian Product Information document, irrespective of the source on which the claim is based.

This responsibility relates not only to the product being promoted, but to any information given or claims made about other products, disease states or conditions. It also applies to tag lines and their ability to be substantiated.

With regard to balance, companies must ensure that adequate safety information is included in relation to efficacy or other promotional claims.

Activities of company representatives must comply with this Code at all times.

1.2 Substantiating Data

1.2.1 Provision of Substantiating Data

Further to the information supplied or generally available, a company will, upon reasonable request, provide healthcare professionals with additional accurate and relevant information about products which it markets, including company information.

All data to substantiate claims must be easily retrievable so that they could be supplied on request within 10 working days. This includes, but is not limited to:

a) where data in support of a medical claim or promotional claim are not available through standard library services;
b) evaluated data contained in an application for registration in accordance with the current or previous TGA guidelines for the registration of products may be used to substantiate claims. A statement that the data are 'confidential' will not be accepted; and
c) 'data on file' or 'in press'.

If the information on which a claim is based may not be released, for example an 'in press' article which is subject to confidentiality provisions, then that information may not be used to substantiate a claim for the purposes of satisfying this Section. Papers cited as 'in press' must have been accepted for publication and be available as a final approved manuscript or in proof form. Papers submitted for publication and not yet accepted by a journal may be identified only as 'unpublished data', 'personal communication', 'unrefereed data', or in similar terms.

1.2.2 Level of Substantiating Data

Any information used to support a medical claim or promotional claim must include sufficient detail and be of adequate quality to allow evaluation of the validity of results and hence the claim. Such substantiating information must not rely solely on 'data on file'.

Evidence to support any claim that will have a significant impact on the prescribing of a product must be unequivocal and the highest quality. It should not rely solely upon evidence from sources such as poster presentations or abstracts that do not provide sufficient information to assess the veracity of the claim. These information sources can be used as secondary references to support claims.

Claims based on well-designed meta-analyses and systematic reviews can have greater influence on prescribing and therefore need to be used appropriately. A systematic review evaluates both positive and negative aspects of the whole body of evidence. Selective use of consistent positive results while neglecting consistent negative results from a systematic review or meta-analysis is not appropriate.

It is only appropriate to extrapolate from surrogate endpoints where a link between the surrogate endpoint and the clinical outcome has been generally accepted and is supported by the body of evidence.

Claims based on pre-specified secondary endpoints where the primary endpoints are not met in a particular study must:

- be consistent with the body of evidence; and
- accurately reflect the conclusion of the study; and
- be clear to a reader that the primary endpoint was not met.

The use of *post-hoc* analyses is acceptable, but must be clearly identified, used in context of the primary end point(s) and appropriately qualified. It should be made clear to the reader if the primary endpoint(s) of the original study was not met or if the claims based on *post-hoc* analyses are inconsistent with the primary endpoint(s).

Cost effectiveness data may be used to substantiate claims; however these data must conform with Sections 1.1, 1.2, 1.3, 1.6 and 1.8 of this Code.

In determining whether sufficient evidence is available to support a claim, companies should have regard to issues such as, but not limited to: the study design, the number of patients, the location of any trial or study, its primary purpose and end points, the results, the reputation and qualifications of the people involved in the study or trial, its consistency with the current body of evidence and where (for example peer reviewed journal or pay journal) or whether it has been published.

1.3 False or Misleading Claims

All information, claims and graphical representations provided to healthcare professionals or members of the general public must be current, accurate, balanced and must not mislead either directly, by implication, or by omission.

All claims must be referenced. The reference must be stated using a type size not less than 1.5 mm based on the font's lower case 'e' for printed materials. A clear style of typeface must be used with adequate space between lines. Legibility is impaired by use of 'condensed' or 'narrow' fonts; by use of upper case letters only; or by use of half-tone rather than solid print.

If qualifying statements are used with a medical claim or promotional claim, they should be linked to the relevant claim with a readily identifiable symbol such as an asterisk or a similar device. Qualifying statements must appear directly below or adjacent to the claim using a type size not less than 3 mm based on the font's lower case 'e' for printed materials.

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 must not be cited.

Animal or laboratory data must 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 symbol such as an asterisk or a similar device.

1.4 Unapproved Products and Indications

A product or indication that has not been approved for registration in Australia by the Therapeutic Goods Administration (TGA) must not be promoted.

Where a company has been formally advised by the TGA that a product has been entered on the Australian Register of Therapeutic Goods (ARTG) and its Product Information containing the approved indications has been finalised, it is considered approved for registration for the purpose of this Code.

Upon receipt of an unsolicited request, company personnel from the medical department, including field based medical personnel, may provide information on unapproved products or subjects not covered by the Product Information to healthcare professionals, such as unapproved indications. Companies may make such information available in company Medical Information websites and mobile applications provided that:

- these responses are only accessible after the healthcare professional has entered relevant search terms for the response (at least two keyword search terms must be entered before any results are returned);
- the responses must include disclaimers that clearly identify any information that is for unapproved products or indications and state that the provision of this information is not intended to advocate any use not covered by the Product Information;
- the dataset which can be searched must consist mainly of information regarding use covered by the Product Information;
- the website must not contain any advertising or promotional information; and
- the website is password protected to only allow access to healthcare professionals.

Medical Information provided in this manner is considered to be unsolicited**.** Under no circumstances may the availability of information on unapproved product and indications from the medical department or via Medical Information services (including Medical Information websites) be promoted to healthcare professionals. This does not preclude the provision of the contact details for Medical or Medical Information services (including Medical Information websites) to healthcare professionals, however these contact details may only be provided along with a general statement such as “For more information contact/visit ...”.

Any information provided about unapproved products or indications must be selected and/or prepared by the medical department and any resulting dialogue about an unapproved product or indication with the healthcare professional should be with medical department personnel and not a member of a commercial function or team.

Companies sponsoring a healthcare professional to speak at a company-sponsored educational event or Congress must ensure, as a condition of the sponsorship, that the healthcare professional is familiar with the approved indications for relevant products and is aware of the obligation not to promote unapproved company products or indications. Companies must be able to produce documentary evidence of this briefing and its contents which can be publicly disclosed if required.

- This applies irrespective of whether the company has provided the healthcare professional with a presentation or other material.
- This 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.

In the case of International Congresses and Australasian Congresses held in Australia, where a product is registered in a country from which a significant number of attendees originate, but the product or indication is not approved in Australia:

- starter packs of products may be displayed, but not distributed; and
- educational and promotional material may be made available in accordance with Section 9.6 – Trade Displays.

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.

1.5 Good Taste

All promotional and educational material (including graphics and other visual representations) must conform to generally accepted standards of good taste and recognise the professional standing of the recipients.

These materials must not contain anything that would be likely to cause serious or widespread offence taking into consideration prevailing community standards.

1.6 Unqualified Superlatives

Unqualified superlatives must not be used. Claims must not imply that a product or an active ingredient is unique or has some special merit, unless its relevance to a clinical outcome can be substantiated with evidence of adequate quality.

Use of the definite article to imply a special merit, quality or property for a product is unacceptable if it cannot be substantiated. For example, a claim that a product is ‘The analgesic’ implies that it is in effect the best, and is not acceptable under this provision.

The words ‘safe’ or ‘unique’ must not be used without qualification.

Although in some circumstances ‘unique’ may be used to describe some clearly defined special feature of a product, in many instances it may be taken as implying a general superiority. In such instances, this is unacceptable unless the claim can be supported in every respect.

1.7 New Products

The word ‘new’ must not be used to describe any product, presentation, PBS listing or therapeutic indication that has been:

i. available to be prescribed and supplied for more than 12 months in Australia; or
ii. promoted for more than 12 months in Australia;

whichever is the period that expires first.

Companies must not promote that a product will be listed on the Pharmaceutical Benefits Scheme (PBS), Repatriation Pharmaceutical Benefits Scheme (RPBS), National Immunisation Program (NIP) or Life Saving Drugs Program prior to receiving formal written advice from the Department of Health stating the listing date.

1.8 Comparative Statements

The intention of this provision is to prohibit unfair and unjustified comparisons with the products or activities of a competitor.

Care must be taken to ensure that any comparison properly reflects the body of evidence and does not mislead by distortion, by undue emphasis or in any other way. Comparisons of products must be factual, fair, capable of substantiation, referenced to its source; and must not be disparaging. ‘Hanging’ comparatives – those that merely claim that a product is better, stronger, more widely prescribed etc. must not be used.

Claims of comparative efficacy or safety must not be based solely on a comparison of Product Information documents that does not reflect the general literature, as those documents are based on different databases and are not directly comparable. This applies to Australian as well as overseas Product Information documents. Comparative claims must be substantiated with respect to all aspects of efficacy or safety. Where a comparative claim relates to a specific parameter, any claims must be clearly identified as pertaining to that parameter.

The accepted level of statistical significance is $p < 0.05$. If comparative data that are not statistically significant are used, such data must comply with the following conditions:

- the lack of significance must be stated explicitly, it is insufficient to state the p value; and
- the data must not be used to generalise or to indicate superiority or inferiority.

If comparative data are used where the relevant study does not include a statement of the significance or lack of significance of the comparative data, the lack of a p value must be explicitly stated.

A statement that the difference is not statistically significant or p value not stated must be linked to the original claim by a readily identifiable symbol such as an asterisk or a similar device, and appear directly below or adjacent to the claim using a type size not less than 3 mm based on the font’s lower case ‘e’ for printed materials.

Care should be taken to distinguish between mathematically determined statistical significance on the one hand and clinical significance on the other.

‘Data on file’ when used to substantiate comparative statements must comply with the requirements of Section 1.2.

1.9 Imitation

Promotional information should not imitate the devices, copy, slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.

2. Promotional Material Directed at Healthcare Professionals

General Principles

The content of all promotional material provided to healthcare professionals must be current, accurate, balanced and fully supported by the Australian Approved Product Information. All promotional material must comply with Section 1 of this Code.

Wherever a promotional claim is made for a prescription product, it must be accompanied by the appropriate form of Product Information.

All promotional material directed at healthcare professionals must include a clear and prominent statement drawing attention to the Pharmaceutical Benefits Scheme (PBS) listing and restrictions or its non-availability via the PBS. To satisfy the requirements of this Section the requirements for the disclosure of this information, including the size of the PBS disclosure statement, can be found in the current *Code Guidelines*.

Any limitations to the terms of PBS listing should be clearly disclosed and easily identifiable by a reader. No attempt should be made to minimise this disclosure as it should be a prominent feature of any promotional material and a genuine communication vehicle to advise prescribers of this important information. The disclosure of this information must accurately reflect the current PBS listing, but may be a paraphrase or précis of that information. Other funding information can be added to the body of the promotional item for example, National Immunisation Program or the Life Saving Drugs Program.

For prescription products that have a boxed warning included in their Product Information, all promotional material must include the boxed warning or a prominent statement drawing attention to the boxed warning.

Promotional material must be clearly distinguishable as such. Advertisements in any media should not be designed to resemble editorial matter unless clearly identified as an advertisement or advertorial. For information pertaining to advertisements in different media please refer to Sections 2.1 to 2.5 of this Code.

A clear style of typeface must be used with adequate space between lines. Legibility is impaired by use of ‘condensed’ or ‘narrow' fonts; by use of upper case letters only; or by use of half-tone rather than solid print.

2.1 Print Media

The type size requirements for advertisements in print media are summarised in Table 1 on page 17.

All Text, including mandatory information, such as any form of Product Information, qualifying statements, and references should appear on a plain background with text colour sufficiently contrasting for legibility. The orientation of the text should be the same as that of the main text of the advertisement. Qualifying statement must appear in a type size of not less than 3 mm as measured by the font’s lower case ‘e’.

All advertisements in print media must conform with the requirements of one of the following categories.

2.1.1 Journal advertisements directed at healthcare professionals

Journal advertising must conform with the requirements of one of the following categories. The information required must appear in each publication on a plain background sufficiently contrasting for legibility. The orientation of the text should be the same as that of the main text of the advertisement. For mandatory information set out in Sections 2.1.1.1, 2.1.1.2, 2.1.1.3, 2.1.1.4 and 2.1.1.5 of this Code the minimum font size as measured by the font’s lower case ‘e’ must conform to the specifications in each section.

2.1.1.1 Primary Advertisement

A Primary advertisement is the type of advertisement that must be used for advertising all new chemical entities or new indications for a period of 24 months from the date of first advertising in medical publications, or longer at the discretion of the company.

A Primary advertisement must also be used for a period of 12 months or longer at the discretion of the company following a change of clinical significance.

A Primary advertisement may contain promotional claims.

A Primary advertisement must contain the following information within the body of the advertisement:

a) the brand name of the product (minimum size 1.5 mm);
b) the Australian Approved Name(s) of the active ingredient(s) placed adjacent to the most prominent presentation of the brand name (minimum size 1.5 mm);
c) all PBS listings, including any restrictions (minimum size 2 mm);
d) the Product Information or the Minimum Product Information (minimum size 1.5 mm);
e) the name of the supplier and the city, town or locality of the registered office (minimum size 1.5 mm).
f) a clear and unambiguous statement for prescribers to review the Product Information before prescribing (minimum size 3 mm);

If the Minimum Product Information is printed within the body of the advertisement a company may also:

- make reference to the Product Information elsewhere in the journal; and/or
- provide a URL or similar mechanism to immediately access the current Product Information on a company website or other electronic storage database; and/or
- include a telephone number for the company medical information service (e.g. a 1800 number) to enable a healthcare professional to request a copy of the Product Information.

When directing the Healthcare Professional to the Product Information, a company must do so in one of the following ways (minimum size 3 mm):

a) *"Please review Product Information before prescribing. In this publication, Product Information can be found …"*

At this point "…", insert the page number of the publication where the Product Information can be found or reference to the Product Information section or Advertisers Index. If the Product Information is provided within the journal, it must form a fixed part of the journal.

or

b) *"Please review Product Information before prescribing. The Product Information can be accessed at …"*

At this point "…", insert the URL where the Product Information can be found. If a hyperlink or similar mechanism is included, it is the company's responsibility to ensure that the Product Information is accessible and current.

or

c) *"Please review Product Information before prescribing. To have a copy of the Product Information sent to you, telephone …"*

At this point "…", insert the freecall 1800 number for the company's medical information department. If a paper copy of the Product Information document is requested via the medical information department it should be sent within five working days.

A summary of all requirements for a Primary advertisement can be found in Table 1 on page 17.

Where an advertisement consists of a double sided or multiple page copy, the information contained on each individual page must not be false or misleading when read in isolation.

2.1.1.2 Secondary Advertisement

A Secondary advertisement is designed to reinforce information about a product, and may contain promotional claims. The use of a Secondary advertisement in any single issue of a publication that does not also contain a Primary advertisement is not permitted.

A Secondary advertisement must contain the following within the body of the advertisement:

a) the brand name of the product (minimum size 1.5 mm);
b) the Australian Approved Name(s) of the active ingredient(s) placed adjacent to the most prominent presentation of the brand name (minimum size 1.5 mm);
c) all PBS listings, or reference to the Primary advertisement (minimum size 2 mm);
d) a clear and unambiguous statement for prescribers to review the Product Information before prescribing (minimum size 3mm);
e) the name of the supplier and the city, town or locality of the registered office (minimum size 1.5 mm); and
f) a reference to the location of the Primary advertisement or the Product Information index or Advertisers index; or provide a URL or similar mechanism to immediately access the current Product Information on a company website or other electronic database. (minimum size 3 mm)

A summary of all requirements for a Secondary advertisement can be found in Table 1 on page 17.

2.1.1.3 Short Advertisement

A Short advertisement is designed to remind a prescriber of a product's existence, but must not contain promotional claims. A promotional tagline must not be used in a Short advertisement.

The use of a Short advertisement in any single issue of a publication that does not also contain a Primary advertisement is not permitted:

- for 24 months from first advertising of a new chemical entity; or
- for 12 months following a change of clinical significance made to the Product Information.

A Short advertisement must contain the following within the body of the advertisement:

a) the brand name of the product (minimum size 1.5 mm);
b) the Australian Approved Name(s) of the active ingredient(s) placed adjacent to the most prominent presentation of the brand name (minimum size 1.5 mm);
c) all PBS listings, or reference to the Primary advertisement if it is included in the same publication (minimum size 2 mm);
d) a statement referring to the location of Product Information in the Primary advertisement, Product Information section, Advertisers index or Reference Manual; or provide a URL or similar mechanism to immediately access the current Product Information on a company website or other electronic storage database (minimum size 3 mm);
e) the name of the supplier and the city, town or locality of the registered office (minimum size 1.5 mm); and
f) a statement to the effect that further information is available on request from the supplier (minimum size 3 mm).

A Short advertisement may also include:

a) up to 5 words describing therapeutic class, but without the use of promotional phrases;
b) graphics;
c) a statement of available dosage forms; and
d) the website address of the company.

A summary of all requirements for a Short advertisement can be found in Table 1 on page 17.

2.1.1.4 Company Commissioned Articles (also known as advertorials)

Company commissioned articles must be identified as such in a type size of not less than 3 mm as measured by the height of the font's lower case 'e'.

The company which is responsible for the insertion of the company commissioned article must be clearly identified at either the top or the bottom of the company commissioned article in a type size of not less than 1.5 mm as measured by the font's lower case 'e'.

Company commissioned articles must conform to all relevant provisions of Section 1 of this Code.

Statements by third parties, which are quoted in company commissioned articles, must comply with the relevant provisions of Sections 1 and 2 of the Code.

Where promotional claims are made in company commissioned articles, the article must comply with the requirements for a Primary (Section 2.1.1.1) or Secondary advertisement (Section 2.1.1.2). The requirements for a Secondary advertisement would apply where there is a Primary advertisement elsewhere in the publication.

2.1.1.5 Reference Manual Advertising

The *MIMS, e-MIMS* and *AusDI* currently satisfy the criteria for reference manuals. For the purposes of this Section, *MIMS Annual*, *e-Mims* and *MIMS Abbreviated* are regarded as one reference manual.

Primary advertisements in reference manuals must conform to the requirements of Sections 2.1.1.1(a), (b), (c) and (f). These advertisements must also include reference to the product's Therapeutic Class Number or to the page number on which the relevant Product Information is located.

Short Advertisements in reference manuals must conform to the requirements of Sections 2.1.1.3 (a), (b), (c) and (d).

TABLE 1 **Summary of requirements for Journal and Reference Manual Advertising**

(For full details please refer to Section 2.1 and 3.3)

Primary Advertisement	**Secondary Advertisement**	**Short Advertisement**	**Reference Manual (*MIMS*, *e-MIMS* and *AusDI*)**
Use:			
Primary advertisement is mandatory for advertising of all new chemical entities or the advertising of new indications • For 24 months from the first advertising of a new chemical entity • For 12 months following a change of clinical significance made to the PI After 24 Months It is not mandatory to use a Primary advertisement; however, a company can choose to use a Primary advertisement at its discretion. Change in Clinical Significance Primary advertisement must be used for 12 months following a change in clinical significance. See also Section 3.3	The sole use of a Secondary advertisement in a single issue of a publication that does not also contain a Primary advertisement is not permitted at any time, irrespective of the time since first advertising.	The sole use of a Short advertisement in a single issue of a publication that does not also contain a Primary advertisement is not permitted • For 24 months from the first advertising of a new chemical entity • For 12 months following a change of clinical significance made to the PI After 24 Months A Short advertisement can be used in a journal without the requirement for a Primary advertisement in the same publication.	For the purposes of this section, *MIMS Annual and MIMS Abbreviated* are regarded as one reference manual.
Promotional Claims:			
May contain promotional claims **Must** conform to provisions of Section 1	**May** contain promotional claims **Must** conform to provisions of Section 1	**Must not** contain any promotional claims	Same as Primary and Short advertising in journals
Advertisements must contain:			
Brand Name of the product	Brand Name of the product	Brand Name of the product	Brand Name of the product
Australian Approved Name(s) of the active ingredient(s) placed adjacent to the most prominent presentation of the brand name	Australian Approved Name(s) of the active ingredient(s) placed adjacent to the most prominent presentation of the brand name	Australian Approved Name(s) of the active ingredient(s) placed adjacent to the most prominent presentation of the brand name	Australian Approved Name(s) of the active ingredient(s) placed adjacent to the most prominent presentation of the brand name
Name of supplier and the city, town, locality of the registered office	Name of supplier and the city, town, locality of the registered office	Name of supplier and the city, town, locality of the registered office	Name of supplier and the city, town, locality of the registered office
Clear and unambiguous statement for prescribers to review the PI before prescribing.	Clear and unambiguous statement for prescribers to review the PI before prescribing.	Statement to the effect that further information is available from the supplier.	Statement to the effect that further information is available from the supplier.
The Product Information or Minimum Product Information must appear in the body of the advertisement. The Primary advertisement must include instructions for accessing Product Information as selected from those set out in 2.1.1.1 If the Minimum Product Information is printed within the body of the advertisement a company **may** also make reference to the Product Information elsewhere in the journal or provide a URL or similar mechanism to immediately access the Product Information on a company website or within electronic storage database. A telephone number may also be included which enables a healthcare professional to request a copy of the Product Information.	A reference to the location of the Product Information in the: • Primary advertisement; • Direct hyperlink or URL; • Product Information section; or • Advertisers index It is the company's responsibility to ensure that the Product Information is in fact immediately accessible and current e.g. on a company website or within electronic storage database (minimum size 3 mm)	A reference to the location of the Product Information in the: • Primary advertisement; • Direct hyperlink or URL; • Product Information section; or • Advertisers index It is the company's responsibility to ensure that the Product Information is in fact immediately accessible and current e.g. on a company website or within electronic storage database (minimum size 3 mm)	Reference to product's Therapeutic Class Number or the page number on which the relevant Product Information is located.
All PBS listings, including any restrictions Further information on the formatting of the PBS disclosure information can be found in the *Code Guidelines*.	All PBS listings, including any restrictions; or reference to the Primary advertisement. Further information on the formatting of the PBS disclosure information can be found in the *Code Guidelines*.	All PBS listings, including any restrictions; or reference to the Primary advertisement. Further information on the formatting of the PBS disclosure information can be found in the *Code Guidelines*.	All PBS listings, including any restrictions; or Reference to product's Therapeutic Class Number or the page number on which the relevant PBS information is located. Further information on the formatting of the PBS disclosure information can be found in the *Code Guidelines*.

Primary Advertisement	Secondary Advertisement	Short Advertisement	Reference Manual (MIMS, e-MIMS and AusDI)
Advertisements <u>may</u> also contain			
		• Up to 5 words describing the therapeutic class (no promotional claims or phrases permitted); • Graphics; • A statement of available dosage forms; and • Website address of the company	
Font/Text Size Summary			
• Font/type size refers to the lower case 'e' • Product Information – 1 mm (minimum size) • Minimum PI – 1.5 mm (minimum size) • Statement "Before prescribing please review the Product Information" – 3 mm (minimum size) • Qualifying Statement – 3 mm (minimum size) • Reference to PI if not included in the body of the advertisement – 3 mm (minimum size) • Hyperlink or URL to Product Information – 3 mm (minimum size) • Minimum size for any text in a print advertisement – 1.5mm (minimum size) • PBS Box text – 2 mm (minimum size)			

2.1.2 Printed promotional material provided to, or used for discussion with, a healthcare professional

This section applies to items which contain promotional claims, such as leave behinds, detail aids, retained sales aids, leaflets and other materials prepared by companies based on the available literature and intended for distribution to healthcare professionals.

All items of printed promotional material provided to, or used for discussion with a healthcare professional, must conform with the provisions of Sections 1 and 2.1.2 of this Code. The information required must appear in each item on a plain background with text colour sufficiently contrasting for legibility. The orientation of the text should be the same as that of the main text of the advertisement. For mandatory information set out in Sections 2.1.2 (a) – (f) the minimum font size as measured by the font's lower case 'e' must conform to the following specifications.

Qualifying statements must appear in a type size of not less than 3 mm as measured by the font's lower case 'e'.

All printed promotional material to be provided to, or used for discussion with a healthcare professional must include the following information within the body of the item:

a) the brand name of the product (minimum size 1.5 mm);
b) the Australian Approved Name(s) of the active ingredient(s) placed adjacent to the most prominent presentation of the brand name (minimum size 1.5 mm);
c) all PBS listings, including any restrictions (minimum size 2 mm);
d) Minimum Product Information (minimum size 1.5 mm);
e) the name of the supplier and the city, town or locality of the registered office (minimum size 1.5 mm);
f) a clear and unambiguous statement for prescribers to review the Product Information before prescribing (minimum size 3 mm); and
g) the date that the material was prepared or last revised.

In addition to the inclusion of the Minimum Product Information, in the body of the item of printed promotional material, the healthcare professional must be given immediate access to the Product Information. This may be achieved by:

a) including a URL or similar mechanism to the current Product Information on a company website or other electronic storage database and/or a telephone number for the company medical information service (e.g. a 1800 number) to enable the healthcare professional to request a copy of the Product Information; or
b) providing a paper copy of the current Product Information with the promotional item.

If a URL or similar mechanism is included, it is the company's responsibility to ensure that the Product Information is accessible and current.

If a paper copy of the Product Information document is requested via the medical information department, it must be sent within five working days.

Where multiple forms of promotional materials for the same product are distributed at one time, the Product Information must be included or offered at least once if the materials do not contain a hyperlink or URL where the Product Information is immediately accessible.

A summary of all requirements for printed promotional material can be found in Table 2 on page 20.

2.1.3 Mailing of printed promotional material to healthcare professionals

Printed promotional material mailed to a healthcare professional must comply with all relevant provisions of Sections 1 and 2.1.2 of this Code. Inclusion of printed full Product Information documents with mailers is not mandatory. However, Minimum Product Information requirements and immediate access options for the Product Information as part of promotional materials still apply (see Section 2.1.2). Mailings must comply with Australia's Privacy Legislation.

Printed promotional material must only be mailed to those healthcare professionals who have indicated or can reasonably be assumed to have a need for, or interest in, the particular information. Requests by healthcare professionals to be removed from promotional mailing lists must be complied with promptly and no name restored except at the specific request or with written permission.

Mailing lists must be kept up to date.

Items of printed promotional material, including postcards, envelopes or wrappers must not carry matter that might be regarded as promotion to the general public or that could be considered unsuitable for public view.

Any accompanying material sent with mailed printed promotional material must comply with the relevant provisions of the Code as a stand-alone item.

Where multiple forms of promotional materials for the same product are distributed at one time, the Product Information must be included or offered at least once if the materials do not contain a hyperlink or URL to where the Product Information is immediately accessible.

2.1.4 Printed promotional material for display purposes only

This section applies to items which contain promotional claims, such as trade display banners, panels, posters and other materials prepared by companies based on the available literature and intended for display to healthcare professionals.

The font size for information on display items must be such that the information can be easily read from a comfortable distance.

All printed promotional material intended for display purposes must include the following information:

a) the brand name of the product;
b) the Australian Approved Name(s) of the active ingredient(s) placed adjacent to the most prominent presentation of the brand name;
c) all PBS listings, including any restrictions;
d) the name of the supplier and the city, town or locality of the registered office;
e) a clear and unambiguous statement for prescribers to review the Product Information before prescribing: "Please review Product information before prescribing. Product Information is available from the trade display"; and
f) the date that the material was prepared or last revised.

A summary of all requirements for printed promotional material for display purposes can be found in Table 2 on page 20.

TABLE 2 **Summary of Requirements for Printed Promotional Material**

(For full details please refer to Section 2.1.2, 2.1.3 and 2.1.4)

Printed Promotional material for distribution to healthcare professionals	**Printed Promotional material for display purposes**
Examples/types of material	
• Leave behinds • Detail aids • Retained sales aids • Leaflets • Mailed printed material	• Trade display banners • Panels • Posters • Light boxes
Promotional Claims	
May contain promotional claims Must conform to the provisions of Section 1	May contain promotional claims Must conform to the provisions of Section 1
Material must contain within the body of the item	
Brand name of the product	Brand name of the product
Australian Approved Name(s) of the active ingredient(s) placed adjacent to the most prominent presentation of the brand name	Australian Approved Name(s) of the active ingredient(s) placed adjacent to the most prominent presentation of the brand name
All PBS listings, including any restrictions	All PBS listings, including any restrictions
The name of the supplier and the city, town or locality of the registered office	The name of the supplier and the city, town or locality of the registered office
Minimum Product Information	
A clear and unambiguous statement for prescribers to review the Product Information before prescribing	A clear and unambiguous statement for prescribers to review the Product Information before prescribing *"Please review Product Information before prescribing. Product Information is available from the trade display"*
A hyperlink or URL to where the Product Information is immediately accessible and/or a telephone number for the company medical information service (e.g. a 1800 number), if printed copy of the Product Information does not accompany the piece	
The date that the material was prepared or last revised	The date that the material was prepared or last revised
Material accompanying the item	
If there is no hyperlink or URL from which the Product Information is accessible, a paper copy of the current Product Information	
Font/Text Size	
• Font/type size refers to the lower case 'e' • Minimum PI – 1.5 mm (minimum size) • Statement to review Product Information before prescribing – 3 mm (minimum size) • Hyperlink or URL to the Product Information – 3 mm (minimum size) • Minimum size for any text in an item of printed promotional material – 1.5 mm (minimum size) • Qualifying Statement – 3 mm (minimum size) • PBS Box – 2 mm (minimum size)	The font size for information on display items must be such that can be easily read from a comfortable distance.

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

This section applies to advertising in electronic storage (such as CDs, DVDs, USBs, audiotapes, videotapes, electronic tablets or e-reader devices, and smart phone applications) or broadcast media for private professional use by healthcare professionals or for demonstration purposes to groups of healthcare professionals.

Company electronic and audiovisual media must comply with all relevant provisions of Section 1 of this Code. Text that is given prominence in printed forms of promotional materials, such as PBS information, qualifying statements and referring the prescriber to review the Product Information, should be similarly prominent by text size and location in electronic and audio-visual media.

2.2.1 All company electronic and audiovisual media which include information in relation to a product(s) must include or be accompanied by the following information:

a) the brand name of the product;
b) the Australian Approved Name(s) of the active ingredient(s), placed adjacent to the most prominent presentation of the brand name;
c) all PBS listings, including any restrictions, must be listed and/or displayed within the electronic or audiovisual media in a manner that will allow a healthcare professional to read/listen to and understand this information;
d) the name of the supplier and the city, town or locality of the registered office;
e) the Product Information:
   - Where a product(s) is being promoted the Product Information must be offered to an individual reviewing the electronic or audiovisual media, readily accessible via the electronic or audiovisual media or offered to an audience in a group situation on completion of the presentation;
   - Where the Product Information is included in electronic storage systems, instructions for directly accessing it must be clearly displayed; and
f) the date that the material was prepared or last revised.

Where promotional or medical claims are included in the electronic or audiovisual media, details of the substantiating references must be readily accessible via the electronic or audiovisual media.

The mandatory information a), b), c) and d) above, for example, other than Product Information, must appear on screen for not less than ten (10) seconds unless the words are concurrently spoken at a clearly audible rate in a shorter time. Product Information must be made available in a manner that allows the healthcare professional to review the information at their own pace.

The type size and graphics used in all electronic or audiovisual media must be such that allows easy and clear legibility. The resolution provided by different screen sizes should be taken into account when assessing legibility.

2.2.2 If a company is sponsoring any form of third party audiovisual media which includes a product specific section provided by the sponsor, it should also include a reference to the information listed under Section 2.2.1.

Information provided by a company to a third party for inclusion in electronic and audiovisual media must comply with all relevant provisions of Section 1 of this Code.

A summary of all requirements for electronic and audiovisual advertising can be found in Table 3 on page 24.

2.3 Restricted Access Television

This section applies to advertising in restricted access television for private professional use by healthcare professionals or for demonstration purposes to groups of healthcare professionals.

Television advertising is permitted for transmissions restricted to an audience of healthcare professionals. Television advertising must comply with all relevant provisions of Section 1 of this Code.

During or following the promotion, the following items must appear on one screen and are mandatory for all television advertisements irrespective of the other content of that advertisement or the length of time that the product has been advertised:

a) the brand name of the product;
b) the Australian Approved Name(s) of the active ingredient(s) adjacent to the most prominent presentation of the brand name;
c) all PBS listings, including any restrictions;

d) the name of the supplier and the city, town or locality of the registered office;
e) a statement to the effect:
"Please review Product Information before prescribing. Product Information and substantiating references can be obtained from (the company) or by phoning (Telecaster's phone number); and
f) the date that the material was prepared or last revised.

The typeface must be clearly legible and appear on a contrasting background. The background may contain a pack shot or product photograph but no other graphics.

The mandatory items must appear on screen for not less than 10 seconds unless the words are concurrently spoken at a clearly audible rate in a shorter time.

The provisions of this Code, as they apply to Primary advertisements (Section 2.1.1.1) should be applied to restricted access television advertising. However, as it is not practical to display the Product Information or Minimum Product Information in conjunction with a television advertisement the use of a screen containing mandatory information is required.

A summary of all requirements for restricted access television advertising can be found in Table 3 on page 24.

2.4 Internet, Social Media and eNewsletters

This section applies to advertising in websites (including eNewsletters accessible via the internet), podcasts and social media for healthcare professionals only.

2.4.1 Advertisements for healthcare professionals on Company controlled websites and in independent eJournals and eNewsletters

Medicines Australia supports the right of companies to use the internet as a means of providing accurate and scientifically reliable information on products in a responsible manner for the benefit of healthcare professionals.

The promotion of products covered by the Code of Conduct to the general public via the internet would breach Sections 13.3 of the Code and the Commonwealth Therapeutic Goods Legislation which stipulate that prescription products must not be promoted to the public. Provisions pertaining to information available on the internet for the general public can be found in Section 13.8.

Promotional material on products covered by this Code must be accessible only to healthcare professionals, and must be accessible only via a secure system that is designed to prevent access by members of the general public. The intended audience should be readily apparent on the site.

If a website contains promotional material, it must be a secure site that is designed to allow access only to healthcare professionals. A mechanism such as a password protected site or other entry system has been considered to comply with the requirements of this section. An entry system such as a provider number would also be acceptable. The password to gain access to a restricted access site should not be a word that would be easily identifiable, for example the product name.

Any promotional material provided to healthcare professionals via these media must comply with the relevant provisions of Sections 1 and 2 of this Code.

Advertisements for healthcare professionals on company controlled websites and in independent eJournals and eNewsletters which include information in relation to a product(s) must include the following information:

a) the brand name of the product;
b) the Australian Approved Name(s) of the active ingredient(s) placed adjacent to the most prominent presentation of the brand name;
c) all PBS listings, including any restrictions, must be displayed within the advertisement;
d) a clear and unambiguous statement for prescribers to review the Product Information before prescribing and make the Product Information immediately accessible via a hyperlink or URL;
e) identification and details of substantiating references within the body of the Primary advertisement or accessible via a hyperlink or similar mechanism;
f) a statement to the effect that further information is available on request from the supplier;
g) the name of the supplier and the city, town or locality of the registered office; and
h) the date that the material was prepared or last revised.

The type size and graphics used in all internet, eJournal and eNewsletter advertisements must be such that allows easy and clear legibility. Text that is given prominence in printed forms of promotional materials, such as PBS information, qualifying statements and referring the prescriber to review the Product Information, should be similarly prominent by text size and location in advertisements in websites.

Where references to other information sources or internet sites from Company-controlled websites are made, companies must take all reasonable steps to ensure that these information sources and internet sites are appropriate and will enhance appropriate prescribing, dispensing and usage of products in Australia. It must be made clear when the reader is leaving the site or being directed to a site that the company has not developed. Any references or linkages to other reputable information sources must be to sources which provide valuable educational material that would enhance the quality use of products in Australia. When making such a reference or linkage a clear screen displaying the following statement must appear before the reference material is accessed:

"The information a reader is about to be referred to may not comply with the Australian regulatory requirements. Further information relevant to the Australian environment is available from the company or via the Product Information."

It is appropriate for companies to link their websites to the text of the Code of Conduct on the Medicines Australia website. Such a linkage must not be used to imply that Medicines Australia endorses any part of the content of the company's site but to provide information to healthcare professionals on the Code of Conduct and the standards it sets.

2.4.2 Social media

The promotion of products covered by this Code using social media where the general public may have access would be in breach of Section 13.3 of the Code and the Commonwealth Therapeutic Goods Legislation which stipulate that prescription products must not be advertised or promoted to the general public.

All Social Media activities or interactions directed at healthcare professionals must comply with the relevant requirements of Sections 1, 2.4.1 and 4 of this Code and the Social Media principles in Section 13.10 of this Code.

2.4.3 eNewsletters

Company eNewsletters, whether available on-line or sent via email, must comply with the provisions of Sections 1 and 2.4.1 of the Code and the *Commonwealth Spam Act 2003* (the Act).

A summary of all requirements for internet advertising can be found in Table 3 on page 24.

TABLE 3 **Summary of Requirements for Other Media**

(For full details please refer to Sections 2.2, 2.3 and 2.4)

Electronic and Audiovisual media	Restricted access television	Internet, Social Media & eNewsletters
Examples		
• CDs • DVDs • USBs • Audiotapes • Videotapes • Smart phone Applications • Mobile device software and applications • Electronic tablets • E-reader devices	Restricted access television	• Company controlled websites • Independent eJournals and eNewsletters • Company eNewsletters • Podcasts • Social media - Facebook - YouTube - Myspace - Wikis - Twitter
Accessibility of advertisements		
		The promotion of products covered by the Code of Conduct to the general public via the internet, including social media would breach Sections 13.3 of the Code and the Commonwealth Therapeutic Goods Legislation which stipulate that prescription products must not be promoted to the public**.**
		Sites containing advertising of prescription products must be password protected. The password to gain access to a restricted site should not be a word that would be easily identifiable, for example the product name.
Advertisements must contain		
Brand name of the product	Brand name of the product	Brand name of the product
Australian Approved Name(s) of the active ingredient(s) adjacent to the most prominent presentation of the brand name	Australian Approved Name(s) of the active ingredient(s) adjacent to the most prominent presentation of the brand name	Australian Approved Name(s) of the active ingredient(s) adjacent to the most prominent presentation of the brand name
All PBS listings, including any restrictions, must be listed and/or displayed within the advertisement to allow a prescriber to read/listen to and understand this information	All PBS listings, including any restrictions, must be listed and/or displayed within advertisement to allow a prescriber to read/listen to and understand this information	All PBS listings, including any restrictions, must be listed and/or displayed within the advertisement to allow a prescriber to read/listen to and understand this information
Name of the supplier and the city, town or locality of the registered office	Name of the supplier and the city, town or locality of the registered office	Name of the supplier and the city, town or locality of the registered office
The date that the material was prepared or last revised.	The date that the material was prepared or last revised.	Advertisements published on Company controlled websites and in independent eJournals and eNewsletters must include the date that the material was prepared or last revised.
Items for use by individual healthcare professional • Product Information must be readily accessible via the electronic or audiovisual media • Instructions for directly accessing it must be clearly displayed. • Items for use at educational events only • Product Information must be offered to an audience in a group situation on completion of the presentation.	A statement to the effect: *"Please review Product Information before prescribing. Product Information and substantiating references can be obtained from (the company) or by phoning (Telecaster's phone number)."*	A clear and unambiguous statement for prescribers to review the Product Information before prescribing and make the Product Information immediately accessible via a hyperlink or URL.
References		
Substantiating references must be readily accessible via the electronic or audiovisual media	See Product Information statement above	Identification and details of substantiating references within the body of the Primary advertisement or accessible via a hyperlink or similar mechanism.
		A statement to the effect that further information is available on request from the supplier.
Font/Text Size		
The type size and graphics used in all advertisements must be such that allows easy and clear legibility. Text given prominence in printed forms of promotional materials should be similarly prominent by text size and location in electronic and audio-visual media.	The type face must be clearly legible and appear on a contrasting background. The background may contain a pack or product photograph but no other graphics.	The type size and graphics used in all internet advertisements must be such that allows easy and clear legibility. Text given prominence in printed forms of promotional materials should be similarly prominent by text size and location in advertisements in websites.
Timing		
The mandatory items must appear on screen for not less than ten (10) seconds unless the words are concurrently spoken at a clearly audible rate in a shorter time.	The mandatory items must appear on screen for not less than ten (10) seconds unless the words are concurrently spoken at a clearly audible rate in a shorter time.	

2.4.4 Distribution of promotional material to healthcare professionals via email or facsimile

Promotional material emailed or faxed to a healthcare professional must comply with all relevant provisions of Section 1 and the relevant provisions of Section 2.4.1 of this Code and Australia's Privacy Legislation.

Promotional material sent via electronic messaging must also comply with the *Commonwealth Spam Act 2003* (the Act). Under the Act, no person is permitted to send 'spam' being an unsolicited commercial electronic message (which includes emails, instant messaging, SMS and other phone messaging).

Items suggesting a requirement for urgent attention, whether by general mail, facsimile or email of replicas of urgent media are not acceptable for promotional purposes.

All mailing lists (including electronic mailing lists) must be kept up to date.

2.5 Prescribing Software

Advertisements for prescription products must not be placed in any section of prescribing software packages.

A company may pay for the inclusion of medical education for healthcare professionals or patient aids, patient support program registration and patient aids and patient support program materials in a prescribing software package.

Medicines Australia encourages the electronic availability of Consumer Medicine Information (CMI) via prescribing software packages to facilitate the use of this information in consultation with patients.

2.6 Brand Name Reminders

Items formerly known as brand name reminders may not be given to healthcare professionals.

Medical education items can be provided subject to the provisions of Section 9.12 – Gifts and Offers. They must not be provided to individuals for their personal benefit.

Medical education items must not bear the name of any medicine or product. Materials supplied for medical education must include the name of the supplier, and city, town or locality of the registered office.

Healthcare professionals and appropriate administrative staff attending scientific meetings and conferences, promotional meetings and other such meetings may be provided with inexpensive notebooks, pens, lanyards and tote bags for use at such meetings. They must not bear the name of any medicine or product or any information about medicines, but may bear the name of the company providing them in accordance with Section 9.4.9 – Provision of company-branded items.

2.7 Competitions and Quizzes

2.7.1 Competitions for healthcare professionals that include the provision of a prize are not permitted. Companies may offer a quiz for health professionals at a trade display, but no prize may be offered.

A quiz must be clearly separate from market research surveys and starter pack requests.

2.8 Communication with Healthcare Professional Media (primary intended audience healthcare professionals)

2.8.1 Media releases (company initiated communication)

The purpose of a media release is to provide current, accurate and balanced information about products available in Australia and therefore must include information about the product's precautions, adverse effects, warnings, contraindications and interactions.

A company may issue a media release to the healthcare professional media for the following purposes, including, but not limited to:

- announcing a new product, new indication, new dosing, or new formulation;
- announcing a new or changed PBS, Repatriation Pharmaceutical Benefits Scheme (RPBS), National Immunisation Program (NIP) or Life Saving Drugs Program listing;
- announcing a change in funding on the NIP;
- in response to a change to the safety profile of a product;
- to alert healthcare professionals to the results of significant new research, provided such research is consistent with the Product Information.

A media release to the healthcare professional media must comply with the relevant provisions in Sections 1, 2 and 4 of this Code. Where a company pays for space in a journal, this is considered advertising and the requirements of Section 2.1.1 of the Code apply.

2.8.2 Response to healthcare professional media enquiries (reactive communication)

Upon specific request, companies may provide educational material to medical journalists in the same manner as provided to healthcare professionals. Such information must be current, accurate and balanced and comply with the relevant provisions of Section 1 of the Code.

2.8.3 Sponsorship of medical journalists to attend medical conferences

Companies may only sponsor medical journalists writing for publications directed at healthcare professionals to attend medical conferences. No sponsorship should be conditional upon any obligation by the journalist to report on a company's product(s). Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a journalist. The sponsoring company should request that the sponsorship is disclosed. There must be a formal agreement or exchange of letters outlining the sponsorship provided.

3. Product Information for Inclusion with Promotional Material for Healthcare Professionals

All advertising and promotional material for healthcare professionals as described in Section 2 must include the Minimum Product Information. If it is not accompanied by the Product Information it must also include a URL or similar mechanism to immediately access the current Product Information on a company website or other electronic storage database and/or a telephone number for the company's medical information department. It is the company's responsibility to ensure that the Product Information is provided within five working days if requested.

Wherever required, Product Information or Minimum Product Information must appear on a plain background with text sufficiently contrasting for legibility. Major headings should be easily identifiable. To facilitate easy reading, a clear style of typeface must be used with adequate space between lines. Legibility is impaired by use of 'condensed' or 'narrow' fonts; by use of upper case letters only; or by use of half-tone rather than solid print. Dark print on a light background is preferable.

Product Information or Minimum Product Information must not be overprinted or interspersed with promotional phrases or graphics.

3.1 Product Information

Where a Product Information document has been approved by the TGA, that document must be used in full without alteration unless such alteration is approved by the TGA. When used to accompany promotional material, it should appear under the heading *'Approved Product Information'*.

Where a Product Information document has not been approved by the TGA, the document must comply with the format described in the *Australian Regulatory Guidelines for Prescription Medicines*. When used to accompany promotional material, it should appear under the heading *'Full Product Information'.*

The size of the type for the Product Information must not be less than 1 mm as measured by the height of the font's lower case letter 'e'. Where the Product Information is included within the body of an advertisement or item of printed promotional material, it must not be less than 1 mm as measured by the height of the font's lower case letter 'e'.

3.2 Minimum Product Information

The size of the type for Minimum Product Information must not be less than 1.5 mm as measured by the height of the font's lower case letter 'e'.

The Minimum Product Information must include the following information within the body of the advertisement or item of printed promotional material:

a) the approved indication(s);
b) the contraindications;
c) clinically significant precautions;
d) clinically significant interactions;
e) very common and common adverse effects;
f) any boxed warnings that may appear in the Product Information;
g) the dosage and method of use; and
h) a statement to the effect that Product Information is available on request from the company.

Where the Product Information does not include information relevant to these sections, such information is not required to be included in the Minimum Product Information.

If the Product Information includes multiple indications, the Minimum Product Information may include only information relevant to the indication or subset of indications being promoted. However, any boxed warnings that may appear in the Product Information must appear in all versions of the Minimum Product Information.

The Minimum Product Information must be reviewed and, where necessary, updated in a timely manner following a change to the Product Information.

3.3 Changes of Clinical Significance and the addition of a Boxed Warning

Changes of clinical significance relating to product safety are likely to influence the decision to prescribe. They include, but are not limited to, changes to the approved indication(s), contraindication(s) and precautions and the addition of a boxed warning.

Where a change of clinical significance relates to product safety and, in particular, the addition of a boxed warning is incorporated into the Product Information, it should be communicated to relevant healthcare professionals. Companies must communicate a change to the Product Information in accordance with any direction from the TGA.

A summary of all requirements for all forms of Product Information can be found in Table 4 below.

TABLE 4 Summary of requirements for Product Information

(For full details please refer to Sections 3.1, 3.2 and 3.3)

Product Information	**Minimum Product Information**
Where a Product Information document has been approved by the Therapeutic Goods Administration (TGA), that document must be used in full without alteration unless such alteration is approved by the TGA.	a) the approved indication(s); b) the contraindications; c) clinically significant precautions; d) clinically significant interactions; e) very common and common adverse effects; f) any boxed warnings that may appear in the Product Information; g) the dosage and method of use; and h) a statement to the effect that Product Information is available on request from the company.
Primary advertisement Advertisement **must** include the Minimum Product Information within the body of the item + the Product Information **may** also be included as a fixed part of the journal. Printed promotional material mailed to a healthcare professional Item **must** include the Minimum Product Information within the body of the item and e**ither:** • the item **must** contain a hyperlink or URL to where the Product Information is immediately accessible, and a telephone number for the company medical information service (e.g. a 1800 number); **or** • the Product Information **must** be included in the mailing to the healthcare professional if the materials do not contain a hyperlink or URL to where the Product Information is immediately accessible. Printed promotional material discussed with a healthcare professional The Item **must** include the Minimum Product Information within the body of the item and the healthcare professional **must** be given ready access to the Product Information either via a hyperlink or URL to where the Product Information is immediately accessible or a printed copy of the Product Information.	As a minimum all Primary advertisements and items of printed promotional material must always include the Minimum Product Information.
• Font/type size refers to the lower case 'e' • Product Information – 1 mm (Minimum size) • Where the Product Information is included within the body of an advertisement or printed promotional material – 1 mm	• Font/type size refers to the lower case 'e' • Minimum Product Information – 1.5 mm (Minimum size)
Change in Clinical Significance	
Primary advertisement must be used for 12 months following a change in clinical significance Where a change of clinical significance relating to product safety or the addition of a boxed warning is incorporated into the PI, it should be communicated to relevant healthcare professionals. • Companies must communicate a change to the Product Information in accordance with any direction from the TGA.	

4. Educational Material Directed at Healthcare Professionals

4.1 Medical Educational Material

This section includes Educational Material of a medical nature provided via print, audiovisual and electronic media, websites, posters or anatomical models.

All items of an educational nature, whether intended for the education of healthcare professionals or to be used by the healthcare professional in consultation with a patient, must be dedicated to improving the quality use of medicines and/or assisting a patient in their understanding of a condition or disease.

Materials created by or on behalf of a company and supplied to a healthcare professional for medical education must include the name of the supplier, and city, town or locality of the registered office.

Material supplied with medical education may include promotional claims and/or statements, but these accompanying materials must comply with Sections 1, 2 and 3 of the Code. This accompanying material should be clearly identifiable as promotional material.

4.2 Medical Literature and Reprints

This section applies to medical literature, reprints of journal articles and proceedings of educational events distributed via print, audio visual or electronic storage media, websites or podcasts.

In addition to reports prepared by a company, this Section applies to reports prepared by individuals on behalf of companies.

4.2.1 The general interpretation and conclusions of any reprints of journal articles, proceedings of educational events or summaries of literature used in promotion must be consistent with the Product Information for both:

- the sponsor's product(s); and
- any competitor's products with which a comparison is being made.

4.2.2 Quotations from medical literature or from personal communications must accurately reflect the meaning of the author and statistical significance of the study. No part of the reprint or article should be specifically highlighted to draw the attention of the healthcare professional.

4.2.3 Any reports from educational events held or sponsored by a company must be a balanced, true and accurate reflection of that meeting.

4.2.4 Healthcare professionals may request literature on subjects not covered by the Product Information such as unapproved indications. While it is not acceptable to routinely disseminate such literature where unsolicited, it is acceptable to provide such information on request, provided that the literature or accompanying communication clearly identifies that it refers to a product or indication not approved in Australia. If the product is approved in Australia it must be accompanied by the Australian Product Information. Information must be balanced and not promotional and should be distributed by the medical department. Company representatives must not promote the use of unapproved indications or products to healthcare professionals. See Section 1.4 for additional advice.

4.2.5 Reprints themselves do not need to be accompanied by Product Information, but Product Information must be included with any accompanying material (including covering letters) or presentation made which incorporate promotional claims.

4.2.6 If a company sponsors an independently edited supplement this should be stated clearly in the supplement. If a company does sponsor the reporting of a congress or symposium this activity must comply with the requirements of this Code, particularly those contained in Section 1.

4.2.7 Quotations relating to prescription products taken from public broadcasts or private occasions such as medical conferences or symposia should not be reproduced without the written permission of the speaker unless subsequently published. Care should also be taken to avoid ascribing unpublished claims or views relating to prescription products to authors when such claims or views no longer represent, or may not represent, the current view of the author concerned.

Company Representatives

5. Roles and Ethical Conduct

5.1 All material for use by company representatives must conform with the provisions of Sections 1 and 2 of this Code. Verbal statements made regarding a product must also comply with the relevant provisions of Sections 1 and 2 of this Code.

5.2 Company representatives should at all times maintain a high standard of ethical conduct and professionalism in the discharge of their duties. It is recommended that compliance with the Code form part of the overall performance assessment of company representatives.

5.3 It is the responsibility of company representatives visiting a hospital or other institution to make themselves aware of all hospital policies, including operating theatre procedures and conduct their business accordingly.

5.4 Company representatives must not employ any deception to gain an appointment.

5.5 Company representatives should ensure that the frequency, timing and duration of appointment, together with the manner in which they are made, are such as to not cause inconvenience to the healthcare professional. The wishes of an individual healthcare professional, or the arrangements in force at any particular establishment, must be observed by company representatives.

5.6 Detailing of healthcare professionals must not occur in an environment where promotional information could be easily overheard by members of the general public.

5.7 Company representatives, including company agents, must not use the telephone or email to promote products to healthcare professionals except with the documented consent of the healthcare professional.

Where information about a prescription product is provided to healthcare professionals via the telephone or email it must be undertaken in an appropriate and responsible manner so as not to cause any inconvenience or concern to the healthcare professional.

5.8 Wherever a promotional claim is made, the company representative must offer the current Product Information and must advise of all PBS listings and restrictions or make reference to them in any printed promotional material provided.

Where multiple forms of promotional materials for the same product are distributed at one time, the Product Information must be included or offered at least once unless the materials contain a hyperlink or URL to where the Product Information is immediately accessible.

The disclosure of any PBS listing information should be clear and distinct. No attempt should be made to minimise any limitations to the terms of listing. The communication of PBS listing information should be undertaken in a responsible manner to advise prescribers of this important information. The disclosure of this information may be via printed material that complies with the requirements of Section 2.

5.9 Under no circumstances shall company representatives pay a fee, in cash or kind, in order to gain access to a healthcare professional.

The provision of personal domestic type services and products to healthcare professionals, their families or practice staff would be a breach of this section. The provision of a meal, which complies with the requirements of Section 9.4.3, would not be a breach of this Section.

6. Training

6.1 Companies have a responsibility to maintain high standards of ongoing training for company representatives.

6.2 Company representatives should possess sufficient medical and technical knowledge to present information on the company's products in a current, accurate and balanced manner and should be cognisant of all provisions of this Code.

The endorsed Medicines Australia education program provides sufficient background to satisfy the provisions of this Section.

6.3 All medical representatives who have been employed in the Australian prescription pharmaceutical industry since April 1983 are required to have completed or be currently undertaking an endorsed Medicines Australia education program for medical representatives.

No exemptions will be granted for the endorsed Medicines Australia education program as it has been designed to meet the needs of the Australian environment particularly those of healthcare professionals.

6.4 All medical representatives entering the Australian prescription pharmaceutical industry for the first time, whether employed full time or part time, permanent or contracted must enrol in the Code of Conduct component of the endorsed Medicines Australia education program within the first six months of employment and must complete the full program requirements for medical representatives within two years.

6.5 Any person who is directly involved in the development, review and approval of promotional materials and educational materials for the general public (this includes Product Managers, medical, marketing, field based medical personnel or sales staff); or has direct interaction with healthcare professionals for the purpose of promoting a prescription product or providing medical or clinical education; whether part time or full time, must complete the Code of Conduct component of the endorsed Medicines Australia education program within the first 12 months of commencement of employment.

The requirement to complete the Code of Conduct component of the endorsed Medicines Australia education program does not include Managing Directors, Clinical Research Associates, Medical Information or Corporate Affairs personnel unless these personnel are also responsible for the development, review and approval of promotional material and patient education material.

The requirement to complete the Code of Conduct component of the endorsed Medicines Australia education program applies equally to permanent employees or contracted employees. If a medical representative is contracted for a period of less than two years they must be able to demonstrate that they are progressing through the education program in a timely manner and complete the program within the equivalent of two years of permanent employment.

6.6 Any person who is directly involved in the development, review and approval of promotional materials and educational materials for the general public (including Product Managers, medical, marketing, field based medical personnel or sales staff); or has direct interaction with healthcare professionals for the purpose of promoting a prescription product or providing medical or clinical education; whether part time or full time, must also undertake training on a regular basis to ensure that they have sufficient knowledge to comply with the Australian Privacy Legislation and Australian Competition and Consumer Legislation to the extent it is relevant to their roles.

7. Product Starter Packs

7.1 The distribution of starter packs must be carried out in a reasonable manner including compliance with product Conditions of Registration, which control the supply and storage conditions of products, and with QUM principles.

Companies should ensure that they are kept informed of any changes in Commonwealth and State laws concerning the supply of starter packs.

7.2 *[Who can supply]* Starter packs of products may only be supplied by representatives employed by the holder of a manufacturer's licence or wholesale dealer's licence or by authorised company representatives. (Including agents working under a contract to, but not directly employed by, the holder of a manufacturer's licence or wholesale dealer's licence.)

7.3 *[Who can be supplied]* Starter packs may only be supplied at their request to authorised healthcare professionals, including medical practitioners, dentists, veterinarians, hospital pharmacists and nurse practitioners. They may only be supplied when required for any of the following reasons:

a) for immediate use in the surgery for relief of symptoms;
b) for the use of alternative treatments, prior to a prescription being written;
c) for after-hours use; or
d) for gaining familiarisation with products.

Companies must 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 (*http://www.catag.org.au) when supplying starter packs in a public health institution. Distribution of starter packs in hospitals must comply with individual hospital requirements.

Authorised healthcare professionals may be supplied with starter packs of Schedule 4 products. The supply of starter packs of Schedule 8 products is prohibited under State and Territory legislation.

7.4 *[Size]* Starter packs should not exceed 1/3 of the PBS primary quantity for each strength of a product. Primary quantity means most commonly prescribed PBS quantity. For non-PBS products, starter packs should be no larger than 1/3 of the smallest trade pack. Where it is not practical to produce a 1/3 pack, the smallest trade pack may be used.

Examples of products where 1/3 may not be practical would include ear and eye drops, small aerosols, ampoules, products taken in a specific order where pack presentation dictates the order of taking of the product and packs of 15g or less of ointments and creams. Reasons such as cost or availability will not be accepted as being impractical.

7.5 *[Quantity supplied]* The maximum quantity of starter packs to be supplied to an authorised healthcare professional must be at the healthcare professional's discretion, and should reflect their needs until the next visit by their representative.

While the medical practitioner, dentist or hospital pharmacist are required to state the maximum number required, it is not mandatory for the company to supply that quantity. However, the company must not supply in excess of that stated by the medical practitioner, dentist or hospital pharmacist.

7.6 *[Quantity carried]* The maximum quantity carried by a company representative (as described in Section 7.2) at any one time must be an amount that can be reasonably justified for supply to requesting healthcare professionals (as described in Section 7.3). A reasonable maximum quantity would be that required during the course of one business trip, lasting up to one working week. The quantity must be such that QUM principles and a meaningful level of accountability can be followed by the company represented.

7.7 *[Records that must be kept]* A representative authorised to distribute starter packs on behalf of a company must obtain a signed request from a person authorised to receive starter packs, including the name and address of person supplied, name, strength and quantity of the starter packs supplied. The healthcare professional must write the quantity requested and sign the request/receipt form.

Starter packs left with receptionists for the attention of the healthcare professional without a signed request from the healthcare professional will be in breach of the Code of Conduct.

Immediately upon supplying the starter pack/s, an authorised representative of a company must certify that the starter pack/s has/have been delivered.

Authorised representatives must make a record of every starter pack received or supplied together with request forms, consignment notes, invoices and advice notes. Records should be made of the return and disposal of unwanted starter packs.

Companies must keep all records of the request, supply, return and disposal of starter packs for at least two years or longer if required by relevant State or Territory legislation, in a way that they are available for inspection by appropriate authorities. Reconciliation of records should be carried out at least every three months. Companies should develop an appropriate recording system so that if a product recall is necessary, relevant starter packs will be included in the recall.

7.8 [*Labelling]* Primary labelling of all starter packs distributed must comply with the current Therapeutic Goods Order on labelling. Where possible, the Company should allow sufficient space on the primary label for a dispensing label, and the Company should:

- supply pre-printed adhesive labels that comply with the Standard for the Uniform Scheduling of Medicines and Poisons, Appendix L, providing sufficient space for the relevant details to be entered by the dispensing healthcare professional; or
- pre-print the required fields on the primary label.

7.9 *[Product Information (PI) and Consumer Medicine Information (CMI)],* should be offered at the time of distribution or, in the case of CMI, may be included in the starter pack.

7.10 *[Transport and Storage]* Starter packs must be transported and stored in a manner which maintains the storage conditions on the label.

7.11 *[Security]* Representatives must take adequate precautions to ensure the security of starter packs in their possession. When the starter packs are stored other than at a wholesaler, they must be stored in a locked storage facility in accordance with Section 7.10.

It may be necessary to send starter packs by mail to requesting parties, especially in the case of regional centres. When sent by mail or courier, starter packs must be packed so as to be reasonably secure against the package being opened by young children. When mail is used to forward starter packs, registered mail (or its equivalent) must be used. There must be nothing on the packaging which indicates the nature of the contents.

Loss or theft of starter packs must be reported immediately to the employer and the police.

Starter packs must only be kept in a vehicle when it is being used in the course of business. Where starter packs are carried in a motor vehicle by an agent or representative the vehicle shall be kept locked except when the agent or representative is present. Starter packs carried in a vehicle must be kept out of sight of the general public, and must not be transported or stored in the passenger compartment.

7.12 *[Returns & Disposal]* On request companies must promptly accept the return of starter packs of their products. Returned stock must be disposed of in an environmentally sound manner according to the requirements in each State or Territory.

8. Product Familiarisation Programs (PFPs)

8.1 Companies must ensure that all Product Familiarisation Programs have the aim of allowing the medical profession to evaluate and become familiar with a product. Companies should develop a rationale for each PFP which describes the clinical rationale for the program, the total number of patients to be enrolled in the program and the duration that the product will be provided to each patient enrolled in the program based on a clinical assessment.

A company will make available on request the rationale for a PFP without delay, but in any event in no longer than 10 working days from the date of the request.

Company representatives must be aware of individual institutional requirements for Product Familiarisation Programs in specific hospitals, particularly the requirements for management and distribution of the product within the institution.

Company representatives must 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* (http://www.catag.org.au) when undertaking a PFP in a public health institution.

8.2 Companies must not offer any monetary or any other type of reward to healthcare professionals, their families and/or employees for taking part in PFPs.

8.3 PFPs must involve patients being treated for approved indications of the product.

8.4 The company must provide a patient information document to be given to the patient by the healthcare professional which explains that the product will be provided under a PFP for a fixed period, after which it may only be available on a private prescription if it is not reimbursed under the PBS at that time. This document must include a section for the patient to sign indicating their consent to receive the product under the terms described in the patient information document. This consent is to be retained by the healthcare professional and is not to be returned to the company.

8.5 PFPs may be initiated at any time following:

a) the approval of the product for registration; or
b) the approval of new indications.

Only one PFP may be conducted for a particular indication.

8.6 The enrolment period for patients into the PFP must not exceed six months. However, at the expiry of the enrolment period, companies may extend the period of enrolment where there is a strong clinical and/or equity rational for such an extension. The length of time each patient may receive treatment under a PFP should be determined by the clinical rationale.

8.7 Only starter packs that comply with the requirements of Section 7 may be supplied free of charge to prescribers for these programs for use by a patient.

Trade packs may only be supplied free of charge for a PFP if the product is dispensed through a pharmacy or other authorised dispensary or dispenser.

When justified by clinical need, two or more starter packs may be combined in a package with patient education documents which explain that the product is provided under a PFP for a fixed period, after which it may only be available on a private prescription if not reimbursed under the PBS.

The Consumer Medicine Information must be provided with any starter packs or trade packs supplied for a PFP.

A company must not conduct a PFP for a Schedule 8 medicine (drugs of addiction) due to the requirements under State and Territory legislation for the proper control, management, security, and recording of supply of Schedule 8 medicines.

8.8 A PFP will allow an individual healthcare professional to enrol a maximum of 10 patients in the program.

8.9 No formal protocol is required for PFPs where individual patient data is not collected. Aggregated data on a healthcare professional's experience with the product may be collected under a PFP where there is no formal protocol.

A PFP may be set up in a manner that enables the rigorous collection of individual patient data under a formal protocol. The protocol should be reviewed within the company to ensure that patient data collection complies with all relevant guidelines and legislation, particularly with respect to patient consent and data de-identification.

8.10 Suspected adverse drug reactions reported during the PFP must be reported to the TGA in accordance with the current TGA *Australian requirements and recommendations for pharmacovigilance responsibilities of sponsors of medicines* (August 2013).

8.11 On request companies must promptly accept the return of their products supplied under a PFP. Returned stock must be disposed of in an environmentally sound manner according to the requirements in each State or Territory.

9. Relationship with Healthcare Professionals

9.1 General Principles

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

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

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

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

9.2 Medical Ethics

Companies must be cognisant of the ethical requirements and codes of practice which apply to healthcare professionals, other professionals and their business associates within the industry.

Healthcare professionals' names or photographs must not be used in any way without the healthcare professional's documented consent.

Wherever a healthcare professional's name is specified in any kind of promotional material, other than by citation of a published reference, the company should ensure that the healthcare professional is aware of and provides documented approval for the use of his/her name in the context of the entire promotional material. For example, if a doctor agrees to introduce an educational DVD, they should be fully aware of the final content of that DVD, as such a situation would imply endorsement.

The company should also obtain documented approval from the individual if his/her name is used in subsequent promotional material.

9.3 Educational Events

Educational events are important for the dissemination of knowledge and experience to healthcare professionals. The primary purpose of an educational meeting must be the enhancement of medical knowledge and the quality use of medicines.

Company involvement in these events must have the objective of providing current, accurate and balanced medical education in an ethical and professional manner. When organising or sponsoring educational events, it is also important to ensure an appropriate balance between the duration of educational content and any hospitality provided to delegates.

As set out in Section 5, the conduct of company representatives at educational events must be able to withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste.

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

9.4 Company Educational Events Held in Australia

9.4.1 Educational content

The company typically initiates and manages the duration of educational content and the selection of the speakers. Objective evidence of the educational value of the event is required (for example, an invitation or agenda) that clearly describes the educational purpose, content, meeting start and finish times and duration of educational sessions. The educational program should be reviewed and approved through an internal company process.

The identity of the company organising the event must be clearly communicated in all materials relevant to the educational event.

9.4.2 Venue selection

Educational events organised by, or the responsibility of a company, should be held in venues that have suitable facilities to support the provision of education (for example, in a private room with audio-visual facilities). Only healthcare professionals in attendance should be able to hear and view the medical education content and not members of the general public.

If the educational meeting requires 'hands on' training in medical procedures it should be held at a training facility, medical institution or other appropriate facility (for example, a medical practice or hospital).

The choice of venue must be able to successfully withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste. The venue must not be chosen for its leisure, sporting or recreational facilities.

Appropriate venues for company educational events would be conference centres or meeting facilities in a city or suburban hotels or a country centre equivalent. The choice of venues in locations emphasising leisure and sporting facilities is prohibited.

Companies may provide payment to a medical institution of other facility, such as a medical practice or hospital to cover direct costs for the use of the facility for the educational meeting. Any such payment must be commensurate with the actual cost to the medical practice or institution for making their facility available for the meeting.

9.4.3 Meals and beverages

Any meals or beverages offered by companies to healthcare professionals must be secondary to the educational content. Meals and beverages must be appropriate for the educational content and duration of the meeting and should not be excessive.

The maximum cost of a meal (including beverages) provided by a company to a healthcare professional within Australia must not exceed $120 (excluding GST and gratuities). This maximum would only be appropriate in exceptional circumstances, such as a dinner at a learned society conference with substantial educational content. In the majority of circumstances, the cost of a meal (including beverages) should be well below this figure. For hospitality in association with overseas educational meetings this maximum and/or local guidelines should be used as a guide.

9.4.4 Travel

Travel may be provided to delegates of the meeting only if justified by the educational content or the origin of the delegates. Air travel for healthcare professionals attending a company educational meeting must be by economy class only. Travel may only be provided in direct association with the educational event/s, without allowing for more time at the destination than is reasonably justified to enable the healthcare professional to effectively participate in the educational meeting. Any air travel provided must be by the most practical direct route to and from the educational event/s.

9.4.5 Accommodation

A reasonable level of accommodation expenses may be provided to delegates at a company educational meeting only if justified by the time and duration of the meeting or the origin of the delegates.

9.4.6 Entertainment

Interactions between companies and healthcare professionals must not include entertainment.

9.4.7 Remuneration

Delegates must not be paid for their attendance at a company educational event. Any remuneration provided to faculty, speakers and or chair persons must be commensurate with the work involved and should be part of a formal agreement or an exchange of letters (see Section 9.8 Consulting arrangement with healthcare professionals).

9.4.8 Partners, family or guests

A company must not subsidise or pay for the hospitality, travel or other expenses of any guest, family, companion or any other person associated with a delegate attending an educational event. This should be made clear in all invitations to healthcare professionals to educational events.

9.4.9 Provision of company-branded items

A company may provide company-branded pens and notepads to delegates attending a company educational event.

9.5 Sponsored Educational Events

9.5.1 General principles

Companies may sponsor educational events which are organised by a society, college, university or other healthcare professional organisation if the primary objective of the meeting is the enhancement of medical knowledge and improving the quality use of medicines in Australia.

Companies must be fully aware of the activities that any sponsorship will support and be satisfied that they meet the standards established in this section.

Financial sponsorship of an independent educational event must be paid to the organisation arranging or conducting the event. Sponsorship of an independent educational event must not be paid to an individual healthcare professional.

Sponsorship provided for an independent educational event must be reported in accordance with Section 41.2.2 (for events held before 1 October 2015) or Section 41.3.5 (for events held on or after 1 October 2015).

9.5.2 Educational content

The third party organising the educational meeting should independently determine the educational content, select the speakers and invite the attendees. Objective evidence of the educational value of the event is required (for example, an agenda or scientific program) that clearly describes the educational purpose, content, meeting start and finish times and duration of educational sessions. Companies should undertake a review of the educational value prior to agreeing to sponsor the event.

The sponsoring company may propose a speaker for the educational meeting, but the final choice of speakers will be determined by the healthcare professional organisation or nominated faculty.

9.5.3 In-institution educational events

A company may sponsor ‘in-institution’ educational events, such as journal clubs, grand rounds, multidisciplinary and in-service meetings held within the healthcare professional workplace. To qualify for sponsorship, the primary purpose of the event must be the provision of medical education. Sponsorship of ‘in-institution’ meetings lacking medical education is therefore not permitted.

9.5.4 Venue selection

Companies must critically examine the proposed venue of a sponsored educational event outside of the healthcare professional workplace to ensure it is justified and has the facilities to support the provision of education (for example held in a private room with audio-visual facilities).

9.5.5 Hospitality

Companies must critically examine whether any hospitality provided at the sponsored educational event is appropriate for the educational content and duration of the meeting and is secondary to the educational content.

9.5.6 Remuneration

Delegates must not be paid for their attendance at a sponsored educational event. The sponsorship of individual healthcare professionals to attend educational events is covered under Section 9.7. If a company

directly sponsors a speaker or chairperson, any remuneration provided must be commensurate with the work involved and should be part of a formal agreement or an exchange of letters (see Section 9.8 Consulting arrangements with healthcare professionals).

9.5.7 Partners, family or guests

Companies must not subsidise or pay for the hospitality, travel or other expenses of any guest, family, companion or any other person associated with a delegate attending an educational event. This information should be made clear in all invitations to healthcare professionals to attend educational events.

9.5.8 Entertainment

Interactions between companies and healthcare professionals must not include entertainment.

9.5.9 Provision of company-branded items

A company may provide company-branded pens, notepads and/or medical education materials to delegates attending a sponsored educational event.

9.6 Trade Displays

9.6.1 Trade displays which include promotional materials for prescription products must be directed only to healthcare professionals.

9.6.2 Companies must comply with all requirements of the sponsoring organisation when setting up and conducting a trade display

9.6.3 A trade display must include, in a prominent position, the name of the sponsoring company.

9.6.4 All promotional materials used at trade displays must be consistent with the relevant provisions of Sections 1, 2 and 3 of this Code. Product Information for products being promoted must be available from the trade display.

9.6.5 The amount paid to the educational meeting organiser for the trade display is regarded as sponsorship and must be reported in accordance with Section 41.2.2 (for events held before 1 October 2015) or Section 41.3.5 (for events held on or after 1 October 2015).

9.6.6 International and Australasian congresses

Refer to the Section 1.4 - Unapproved Products and Indications that relates to Australian unapproved products and indications.

Companies must ensure that any overseas affiliates sponsoring or involved in such meetings are made aware of and comply with the Code.

<u>International Congresses</u>

In the case of international congresses held in Australia, it may be acceptable to display or supply information for a product not approved for registration in Australia or an unapproved indication of a product registered in Australia, provided that any material used clearly identifies that it refers to a product or indication not approved in Australia, and that the product or indication, as appropriate, is approved overseas.

An appropriately worded label, prominently located, would be sufficient to satisfy this Section. This label must state that the product or indication is unapproved in Australia.

Information regarding products not approved for registration in Australia or non-approved indications of a product registered in Australia must be consistent with the Product Information in the country where the product is registered. Such Product Information must be available and distributed in accordance with this Code of Conduct.

Products not approved for registration in Australia must be approved for marketing in an overseas country from which there are delegates registered at the conference.

<u>Australasian congresses</u>

In the case of Australasian congresses held in Australia, it is acceptable to display or supply educational material for products not approved for registration in Australia or an unapproved indication of a product registered in Australia, if that product or indication has been consented or approved in New Zealand.

Information regarding products not approved for registration in Australia or non-approved indications of a product registered in Australia must be consistent with the Product Information (Data Sheet) in New Zealand. The New Zealand Data Sheet must be available and distributed in accordance with this Code of Conduct.

9.6.7 Gifts or offers provided by a company to encourage a healthcare professional to visit a trade display are prohibited. A company may offer at its trade display the following items provided they comply with relevant section of the Code:

a) Company-branded items of stationery (Sections 9.4.9 and 9.5.9)
b) Educational material directed to healthcare professionals or patients (Section 4)
c) Hospitality at an educational event (Sections 9.4.3, 9.4.4, 9.4.5 and 9.5.5)

Gifts, cash payments and/or donations to charities or societies must not be offered to healthcare professionals to visit trade display stands.

9.6.8 Starter packs must not be made available for collection from unattended trade display stands, nor be supplied to unauthorised or non-healthcare professionals. See also Section 7 starter packs.

Starter packs for products not approved for marketing in Australia must not be provided either at local or international congresses.

9.6.9 Any activities of a company in relation to its trade display must be able to successfully withstand public and professional scrutiny, and conform to professional and community standards of ethics and good taste.

9.7 Sponsorship of Healthcare Professionals to Attend Educational Events (Australasian and International)

9.7.1 The Code of Conduct recognises the contribution of the pharmaceutical industry to the quality use of medicines in Australia through sponsorship of healthcare professionals to attend Australasian and international educational and scientific meetings.

Sponsorship may be provided to a healthcare professional to attend an educational event provided the meeting is directly related to the healthcare professional's area of expertise.

Sponsorship must not be conditional upon any obligation by the healthcare professional to recommend, prescribe, dispense or administer a Company's product(s). Nothing should be offered or provided in a manner, or on conditions, that would interfere with the independence of a healthcare professional's professional practice.

Where companies undertake the sponsorship of a healthcare professional such sponsorship must:

- be able to successfully withstand public and professional scrutiny;
- conform to professional and community standards of ethics and good taste; and
- enhance the quality use of medicines.

9.7.2 Companies must develop clear guidelines in relation to the awarding of sponsorship to healthcare professionals which can be publicly disclosed if required.

9.7.3 There must be a formal agreement or an exchange of letters outlining the nature of the sponsorship provided.

9.7.4 If a sponsored healthcare professional is presenting an oral presentation or poster at an educational or scientific meeting of colleagues and/or peers, the sponsoring company must request that its sponsorship is disclosed.

9.7.5 Sponsored travel for healthcare professionals attending an Australasian educational event must be by economy class only.

Sponsored travel for healthcare professionals attending an international educational event must be by either economy or business class. Travel may only be provided in direct association with the educational event/s without allowing for more time at the destination than is reasonably justified to enable the healthcare professional to effectively participate in the educational meeting. Any air travel provided must be by the most practical direct route to and from the educational event/s.

9.7.6 A reasonable level of accommodation expenses may be provided to sponsored delegates attending an Australasian or international educational meeting. Any accommodation must be reasonable and appropriate for the time and duration of the meeting and the origin of the delegates.

9.7.7 Any meals or beverages offered by companies to sponsored healthcare professionals must be secondary to the educational content. Meals and beverages must be appropriate for the educational content and duration of the meeting and must not be excessive. The maximum cost of a meal (including beverages) provided by a company must comply with Section 9.4.3 for educational events held in Australia. For

hospitality provided to Australian healthcare professionals in association with educational events held overseas the limit stated in Section 9.4.3 applies.

9.7.8 A company must not pay healthcare professionals for their attendance at an Australasian or international educational event.

9.7.9 A company must not subsidise or pay for the hospitality, travel or other expenses of any guest, family, companion or any other person associated with a sponsored healthcare professional attending an Australasian or international educational event.

9.7.10 Sponsorship of healthcare professionals must not include entertainment.

9.8 Consulting Arrangements with Healthcare Professionals

9.8.1 Companies may legitimately seek the services of suitably qualified and experienced healthcare professionals to provide a service, advice and/or guidance on a range of matters. A legitimate need for the services must be clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants.

9.8.2 The purpose and objectives of the interaction must be clearly articulated in a written contractual agreement outlining the nature and duration of the services to be provided.

9.8.3 The number of healthcare professionals retained must not be greater than the number reasonably necessary to achieve the identified purpose.

9.8.4 Any remuneration for services rendered should not exceed that which is commensurate with the services supplied. A company may provide reasonable travel, accommodation or hospitality to consultants in association with the consulting services. Interactions between companies and consultants must not include entertainment.

9.8.5 A company must not subsidise or pay for the travel, hospitality, accommodation or other expenses for any guest, family, companions or other persons associated with the consulting services.

9.9 Advisory Boards

In addition to the requirements in Section 9.8 above, the following criteria apply to Advisory Boards:

9.9.1 A legitimate need for an Advisory Board must be documented and available on request summarising the purpose, objectives and justification for the size and number of Advisory Board(s).

Companies should be cognisant that a document summarising the purpose, objectives and justification of the size/number of the Advisory Board(s) must be publicly available for scrutiny by the Code of Conduct Committee and Complainant should a complaint be lodged.

9.9.2 The formation of multiple Advisory Boards for a single product must be justifiable, for example as a result of registered indications in different medical specialties. Where there are recognised differences in medical practice between States and Territories it may be acceptable to have more than one Advisory Board.

Given the purpose of the Advisory Board, the size of the group must be such that would withstand public and professional scrutiny and adhere to the principles for the quality use of medicines.

9.9.3 Records of the services provided by Advisory Boards must be maintained by the company, including meeting minutes approved by the Chair of the Advisory Board.

9.9.4 Advisory Board Meetings must be held in Australia, at venues consistent with the requirements of Section 9.4.2 of the Code. Two exceptions are allowed, firstly when meetings are held in conjunction with international scientific meetings, and secondly when Australian healthcare professionals are part of an international advisory board organised by a parent or affiliate company.

9.10 Company Supported Medical Practice Activities

A Company may provide financial support for medical practice activities (for example a clinical audit program), provided such programs:

a) are intended to enhance the quality use of medicines through the implementation of an appropriate defined program supported by a clinical rationale;
b) are intended to improve patient outcomes;
c) comply with relevant Privacy legislation; and
d) can successfully withstand public and professional scrutiny.

Medical practice activities may include support for a healthcare professional to co-ordinate the program. Where appropriate, accreditation of the program by a relevant college or society is encouraged. Company

support must not be provided to underwrite a commercial business or generate income for the practice or institution.

Financial support for a medical practice activity must not be conditional upon any obligation by the healthcare professional involved to recommend, prescribe, dispense or administer a Company's product(s). Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's professional practice.

There must be a document outlining the nature of the support provided, which must be available for scrutiny by the Code of Conduct Committee and Complainant should a complaint be lodged. It is recommended that companies seek an acknowledgement from the medical practice to confirm agreement to the practice support.

Medical practice activities must be reviewed and approved through an internal company process.

Consistent with Privacy legislation, any patient level data that is accessible to the Company providing the financial support must be de-identified.

Programs involving sponsorship of practice support staff which involves encouraging the prescribing of a particular product or switching to a particular product would be in breach of the Code.

9.11 Grants and Financial Support

Sponsorship can be provided to organisations that support cultural, educational, philanthropic, sporting and artistic activities or charities but companies must ensure that this association is not undertaken for promotional reasons or used for promotional purposes.

9.11.1 The Code of Conduct recognises the significant contribution of the pharmaceutical industry to the quality use of medicines in Australia through financial support of healthcare professional activities.

A company may provide a grant or financial support provided that the support is made only to a medical practice, hospital, institution or health related organisation:

a) for education, training or academic purposes; or
b) for medical research; or
c) for activities that improve the quality use of medicines; or
d) improve patient outcomes.

9.11.2 Financial support must not be conditional upon any obligation by the healthcare professional to recommend, prescribe, dispense or administer a Company's product(s). Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's professional practice.

9.11.3 Clear guidelines which can be publicly disclosed if required must be developed in relation to the awarding of grants and financial support.

There must be a documented contractual agreement outlining the nature of the grant or financial support provided.

Financial support must be paid to a medical practice or health related organisation, and not paid directly to an individual healthcare professional.

9.11.4 A Company may temporarily loan a piece of equipment to a medical practice or health related organisation, provided it facilitates the quality use of medicines. If the equipment is provided as part of a loan arrangement, the Company must have a mechanism for retrieval of the equipment.

Items provided on permanent loan to a medical practice or health related organisation are regarded as gifts and are subject to the requirements of Section 9.12 of the Code.

9.12 Gifts and Offers

No gift, benefit in kind or pecuniary advantage shall be offered or given to healthcare professionals or to administrative staff as an inducement to recommend, prescribe, dispense or administer a Company's product(s).

This section prohibits the provision of gifts and offers to healthcare professionals unless they meet the requirements of:

a) company-branded items of stationery (Sections 9.4.9 and 9.5.9)
b) educational material directed to healthcare professionals or patients (Section 4)
c) sponsorship to attend an educational event (Section 9.7)
d) hospitality at an educational event (Sections 9.4.3, 9.4.4, 9.4.5 and 9.5.5)

It is not acceptable for a company to provide a gift of flowers, confectionary or other gift that is not related to the practice of medicine or pharmacy to a health professional to mark or acknowledge an occasion such as a family bereavement or special occasion. If a company representative has a personal relationship with the health professional, beyond the working relationship, which may warrant a gift of this kind it may be given by the individual entirely at their own expense.

9.13 Discredit to and Reduction of Confidence in the Industry

Interactions with healthcare professionals must never be such as to bring discredit upon, or reduce confidence in the pharmaceutical industry. A breach of this requirement is a Severe Breach of the Code of Conduct.

Examples of activities that would be seen to bring the industry into disrepute could include:

- activities such the provision of personal services or products to gain access to healthcare professionals; and
- activities where no medical education is delivered and an inducement such as a meal is offered for attendance.

Research

The following provisions apply to Post-Market Surveillance studies and market research conducted by or on behalf of a company, whether the research is carried out directly by the company or by an organisation acting under its direction.

The conduct of clinical research such as Phase I, II and III clinical trials is governed by the Commonwealth therapeutic goods legislation; the ethical principles described in the NHMRC *National Statement on Ethical Conduct in Human Research*; and a number of Guidelines and Policies issued by State and Territory Health Departments.

The Sections of the Code of Conduct that describe the appropriate interactions between a company and healthcare professionals providing consulting services also apply to interactions that occur when conducting clinical research. Any remuneration for services rendered should not exceed that which is commensurate with the services supplied. A company may provide reasonable travel, accommodation or hospitality to clinical research personnel engaged in conducting research. Interactions between companies and these clinical research personnel must not include entertainment. A company must not subsidise or pay for the travel, hospitality, accommodation or other expenses for any guest, family, companions or other persons associated with the person conducting the research.

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

Companies' attention is also directed to the IFPMA/EFPIA/PhRMA/JPMA *Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases* (2009) and *Joint Position on the Publication of Clinical Trial Results in the Scientific Literature* (2010).

10. Post-Marketing Surveillance (PMS) studies

10.1 Post-Marketing Surveillance studies must have scientific or medical merit and objectivity and not be designed for, or conducted as, a promotional exercise.

Companies' attention is also directed to the *Joint TGA-Medicines Australia Guidelines for the Design and Conduct of Company-sponsored Post-Marketing Surveillance (PMS) Studies*.

10.2 Post-Marketing Surveillance studies must be research which is intended to generate data on efficacy and safety parameters of a product that has been approved for registration when used in accordance with the Product Information.

10.3 Post-Marketing Surveillance studies are part of clinical research and the only extent of involvement of Medical Representatives is in recommending or identifying healthcare professionals to participate in the study. The study must be managed through the company's medical department.

10.4 Post-Marketing Surveillance Studies must have a formal protocol, a requirement for data collection and generation of a report.

10.5 When a company is intending to carry out a Post-Marketing Surveillance Study it must advise the TGA of its intention.

10.6 Only patients being treated for approved indications of the product are to be included in the Post-Marketing Surveillance Study.

10.7 Decisions by healthcare professionals to prescribe the product should be based solely on their clinical judgement.

10.8 Starter packs or free trade packs must not be distributed as part of the Post-Marketing Surveillance Study.

10.9 Any payment to a healthcare professional must be commensurate with the work involved and not based upon the number of prescriptions written.

10.10 Suspected adverse drug reactions noted during Post-Marketing Surveillance Studies must be reported to the TGA in accordance with the current TGA *Australian requirements and recommendations for pharmacovigilance responsibilities of sponsors of medicines* (August 2013).

10.11 A prompt report on the outcome of the study should be provided to participating healthcare professionals and the TGA.

11. Ghost Writing

Ghost writing describes inappropriate conduct where the contribution of a writer is not acknowledged in a publication. In contrast to ghost writers, professional medical writers disclose their involvement and funding source and follow ethical publication guidelines. Assistance from professional medical writers is acceptable; assistance from ghost writers is not.

To ensure transparency of authorship or contribution to a publication, companies should follow the principles described in the IFPMA *Joint Position on the Publication of Clinical Trial Results in the Scientific Literature* (2010).

12. Market Research with Healthcare Professionals

This Section deals with market research with healthcare professionals. For information about market research undertaken with members of the general public, see Section 13.10.

When selecting individuals or organisations to undertake any market research activities, companies should ensure that the contracted organisation complies with the Australian Market and Social Research Society *Code of Professional Behaviour*, which is available at www.amsrs.com.au, or an equivalent standard of professional conduct.

12.1 The sole purpose of these activities must be to collect data and not a means to promote to and/or reward healthcare professionals. Market research may be undertaken about an unapproved product or unapproved indication; however, market research must not be used as a means to promote an unapproved product or unapproved indication.

12.2 Market research studies must be clearly identified as such when the initial approach is made to participants. It must be clear to a participant that the market research is being conducted by or on behalf of a pharmaceutical company, but the name of the particular pharmaceutical company need not be disclosed. It is recognised that the disclosure of the name of the company may bias the research.

12.3 Any payment (whether cash or voucher in lieu of cash) must be kept to a minimum and should not exceed a level commensurate with the time involved.

If a voucher is provided in lieu of cash payment, the voucher must be valid only to obtain an item that is directly relevant to the practice of medicine or pharmacy.

A voucher to purchase entertainment, such as movie tickets or lottery tickets is not acceptable.

A donation to a registered charity in lieu of cash payment to a healthcare professional is acceptable if the amount remains commensurate with the work undertaken.

12.4 Promotion should not be represented as market research or research of any type.

12.5 Market research should not be able to be confused with a competition and should be a genuine initiative to collect relevant and useful information to enhance the quality use of medicines.

12.6 Companies must make publicly available details of payments made to healthcare professional consultants selected by the company to participate in market research. Such declarations are not required if the company concerned is not involved in the selection of the healthcare professionals and is not aware of the identities of those participating in the market research.

Where it is required to be disclosed, the information required by Section 12.6 must be included in the report of payments to healthcare professional consultants as required by Section 41.2 (for market research conducted before 1 October 2015) or Section or 41.3 (for market research conducted on or after 1 October 2015).

13. Relationship with the General Public

13.1 General Principles

The promotion of products covered by the Code of Conduct to the general public would breach the Commonwealth Therapeutic Goods Legislation and this Code which stipulate that prescription products must not be promoted to the public.

This Section of the Code of Conduct establishes the ways in which the industry appropriately interacts with members of the general public to enhance the quality use of medicines by being a credible source of current, accurate and balanced information about prescription products approved for use in Australia.

The Consumer Medicine Information and Product Information are credible non-promotional sources of information on a company's products. A company may make these documents available to members of the general public providing they appear in their entire form, and are not amended, abridged or displayed in a promotional manner.

Underpinning all health care is consumers' right to be empowered, heard, respected and encouraged to participate actively in the decision making processes at all stages of their care.

Any activities with, or materials provided to, members of the general public must not bring discredit upon, or reduce confidence in the pharmaceutical industry.

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

Sponsorship can be provided to organisations that support cultural, educational, philanthropic, sporting and artistic activities or charities but companies must ensure that this association is not undertaken for promotional reasons or used for promotional purposes.

13.2 Communication with the General Public

Inquiries regarding the use of products must be handled by appropriately qualified personnel. Requests from individual members of the public for information or advice on the diagnosis of disease or choice of therapy must always be refused and the inquirer recommended to consult their doctor.

Where a specific request is made by a patient or a member of a patient's family about a product which has been prescribed, the company may clarify matters using a Consumer Medicine Information leaflet or a patient aid as described in Section 17, but should otherwise recommend inquirers to consult their doctor.

Companies must ensure that their response to any public inquiry should not be promotional.

13.3 Promotion to the General Public

The promotion of products covered by the Code of Conduct to the general public would breach the Commonwealth Therapeutic Goods Legislation and this Code which stipulate that prescription products must not be promoted to the public.

Prescription products and products which are unscheduled but which can only be obtained via a healthcare professional may be promoted only to healthcare professionals. Any information provided to members of the general public must be educational. Any activity directed towards the general public which encourages a patient to seek a prescription for a specific prescription-only product is prohibited.

Promotion of a medicine delivery device to the general public is permitted in restricted circumstances. Promotion of a medicine delivery device which is used for the administration of a prescription medicine, including Schedule 3 medicines that are predominantly prescribed by a medical practitioner and that is distributed independently from the active ingredient, is permitted as long as the medical device is not branded with the name of a particular medicine. The device must be included on the ARTG as a medical device.

13.4 Relationship with the Consumer Media

It is appropriate and necessary for companies to interact with the lay media (i.e. all media other than that directed to healthcare professionals), either reactively or proactively, as a conduit to the general public. 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.

However, media organisations are wholly independent entities not bound by the provisions of this Code. As a result, while companies cannot control the final output of media coverage, they are wholly and solely responsible to ensure that all their 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

The purpose of a product specific media release is to provide current, accurate and balanced information about products available in Australia (this includes a new product, indication, a change in funding on the National Immunisation Program (NIP), or new or changed PBS, RPBS, NIP or Life Saving Drugs Program listing) and therefore must include information about the product's precautions, adverse effects, warnings, contraindications and interactions.

Media releases must be educational and not include promotional statements or claims, or comparisons with other products. A product specific media release must be in language that reflects current community standards.

A product specific media release issued directly, or through conferences for the lay media to announce a new product or major indication, must not be made known to the general public until the product has been registered in Australia and reasonable steps have been taken to inform the medical and pharmacy professions of its availability.

The product specific media release must contain all of the following in the main body of the release:

- the product's brand name;
- the Australian Approved Name of the active ingredients in the product;
- its approved indications;
- therapeutic class;
- PBS listings and restrictions or a notation if the products is not listed on the PBS; and
- a summary of the side effect profile, product's precautions, adverse effects, warnings, contraindications and interactions consistent with the Minimum Product Information.

The product specific media release must be accompanied by a copy of the product's current Consumer Medicine Information or a direct link to a website where this is available.

A product specific media release may also include:

- a non-comparative description of the mechanism of action;
- price to the patient; and/or
- date of product/indication availability.

A product specific media release must not include:

- promotional statements or claims;
- comparisons with other products;
- quotes from experts, opinion leaders or patients that are promotional or comparative in nature; and/or
- pack shots (an image of the product packaging).

Companies are encouraged to seek the non-binding advice of the Medicines Australia Chief Executive or delegate prior to arranging press statements or media conferences.

No statements or comments should be initiated by a company regarding any products that are not approved for marketing in Australia but are available in overseas countries.

This does not prohibit a company listed on the Australian Stock Exchange issuing a non-promotional product specific media release in line with the continuous disclosure requirements of the Australian Stock Exchange. This media release must follow the principles in the Code of Best Practice for Reporting by Life Science Companies. The Code can be accessed at http://www.ausbiotech.org/

13.4.2 No other product specific media releases are permitted. It is acceptable to respond to media enquiries, comment to the journalist or editor on published articles containing incorrect information and respond to inquiries from members of the general public in an educative and non-promotional manner.

13.4.3 Product specific media releases should not be accompanied by any material which encourages or is designed to encourage the use of any prescription product. Its purpose should be solely educational and informative.

13.4.4 Companies are always responsible for all material prepared for the media by the agencies engaged by them.

13.4.5 If a health professional or a member of the general public is asked by a company to speak to the media, or is recommended to a media outlet by a member company, the company is responsible for ensuring that the spokesperson is fully briefed on the Commonwealth Therapeutic Goods Legislation and the Code, which stipulate that prescription products must not be promoted to the general public. Companies must be able to produce documentary evidence of this briefing and its contents, which can be publicly disclosed if required.

13.4.6 A company product specific media release must be made available upon reasonable request.

13.5 General Media Articles

General media articles concerning specific prescription products must not be initiated by companies.

Companies should not attempt to encourage the publication of general media articles or its content with the aim of promoting their products, but may offer to provide educational material or review copy to ensure accuracy.

13.6 Educational Information available to the General Public

It is acknowledged that members of the general public should have access to information on medical conditions and the treatments which may be prescribed by their doctors. The purpose of such information should be educational and should encourage patients to seek further information or explanation from the appropriate healthcare professional.

In addition, the following criteria should be satisfied:

a) The educational material must be current, accurate and balanced;
b) The educational material must not focus on a particular product, unless the material is intended to be given to the patient by a healthcare professional after the decision to prescribe that product has been made (See Section 13.7 – Materials for Use with Patients (Patient Aids));.
c) Educational material may include descriptions of the therapeutic category, medical condition and a discussion of the relevant clinical parameters in general;
d) The educational material must include the name and the city, town or locality of the registered office of the supplier of the material, but this information should not be given prominence; and
e) The educational material must include a statement directing the patient to seek further information about the condition or treatment from his/her healthcare professional.

Such statements must never be designed or made for the purpose of encouraging members of the public to ask their doctor to prescribe a specific prescription product.

The tone of the message must not be presented in a way that unnecessarily causes alarm or misunderstanding in the community.

On all occasions the information, whether written or communicated by other means, must be presented in a balanced way so as to avoid the risk of raising unfounded hopes of successful treatment or stimulating the demand for prescription of a particular product.

Examples of patient educational material which would be considered to breach the Code include:

a) use of brand names in a manner that promotes a product rather than as an informative and educational tool; or
b) material which is not educational or contains medically incorrect educational material; or
c) inclusion of response rates for a specific product or comparative claims.

13.7 Materials for Use with Patients (Patient Aids)

Patient aids include written information, password-protected websites providing product-specific information and social media forums with access restricted to patients prescribed a specific product. Patient aids also include items that may assist patients to take or administer their medicine, monitor their treatment, carry or dispose of their medicine, including mobile media applications.

Patient aids that are product specific must be solely intended to provide information for the patient once a decision to prescribe that product has been made.

The content of such material must be designed to assist with patient education, compliance and the quality use of medicines by providing information which clarifies for example, method of action, dose, timing and method of administration, precautions, special instructions and similar information. It must not make comparisons between products or include promotional claims.

Items that are more likely to be used outside the home must not be product branded, but may be branded with a company name and/or a logo.

13.8 Disease Education Activities in Any Media

Disease education activities may provide information, promote awareness and educate the public about health, disease and their management.

13.8.1 Activities must not include any reference to a specific prescription product. The promotion of products covered by the Code of Conduct to the general public via disease education activities would breach Section 13.3 of the Code and the Commonwealth Therapeutic Goods legislation which stipulates that prescription products must not be promoted to the general public.

13.8.2 A disease education activity may make reference to the availability of different treatment options (which may include a range of prescription products/classes and/or alternative treatments such as surgery or over the counter products) but this should not be of such a nature that an individual would be encouraged to seek a prescription for a prescription only product. The linking of a disease education activity to a specific prescription product, such as linking to the Product Information or Consumer Medicine Information, would breach Section 13.3 of the Code and the Commonwealth Therapeutic Goods legislation.

13.8.3 The emphasis of the disease education activity should be on the condition and its recognition rather than on the treatment options. The appropriate treatment for an individual patient is for the healthcare professional to decide in consultation with the patient.

13.8.4 A disease education activity should cover the key characteristics of the disease. It should ensure that the impact/implications of the disease are realistically conveyed without being alarmist.

13.8.5 If discussed, management options should be presented in a comprehensive, balanced and fair manner that does not unduly emphasise particular options or the need to seek treatment.

13.8.6 The language used should be designed to convey key messages clearly, supported by appropriate design and formatting appropriate for the intended audience.

13.8.7 The name of the pharmaceutical company must be identified on any disease education activity but should not be given prominence.

13.9 Use of the Internet

Medicines Australia supports the right of companies to use the internet as a means of providing accurate and scientifically reliable information on products in a responsible manner for the benefit of members of the general public. The promotion of products covered by the Code of Conduct to the general public via the internet would breach Section 13.3 of the Code and the Commonwealth Therapeutic Goods legislation which stipulates that prescription products must not be promoted to the general public.

An advertisement as defined in the *Therapeutic Goods Act 1989* includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.

In providing information to members of the general public via the internet, companies must ensure that the intent of this action is informational and not promotional. Care needs to be taken by companies to ensure that material published is of the kind that it is reasonable to conclude that no intention of promotion exists.

The purpose of this section is to identify how current, accurate and balanced information regarding prescription products available in Australia can be provided via this medium to members of the general public. The intent of the provision of this information must be educational and must never be promotional if it can be accessed by members of the general public.

Where references to other information sources or internet sites are made, companies must take all reasonable steps to ensure that these information sources and websites contain valuable educational material that can be readily understood by members of the general public and would enhance their knowledge of disease states.

13.9.1 The following information may be provided to members of the general public via the internet:

- A brief non-promotional summary of the company's products available in Australia. This information should be current, accurate and balanced and must not be promotional. It must be in accordance with the products' current approved Product Information. It must contain information about the products precautions, adverse effects, warnings and contraindications and interactions and may contain information about current research or clinical data that would assist members of the general public to understand how this product works, its uses and compliance advice. A company website must not directly link disease specific education to the company's prescription products for that condition. Such linkage would be considered to be advertising the prescription medicine, which would be in breach of Section 13.3 of the Code and the Therapeutic Goods legislation.
- In relation to company disease state websites, there should not be a focus on the company's product(s). In discussing prescription product options for the disease state, a company may list all the available products, but must not compare any products. A company sponsored disease state website must not have links to websites with information on a company's product(s). A company disease education website must not include a product name as its URL. The website should always contain a statement to the effect of *"For further information talk to your doctor."*
- A copy of each product's Consumer Medicine Information (CMI). CMIs must appear in their entirety. They must not be amended, abridged or displayed in a promotional manner. If provided, the Product Information must appear in its entirety. They must not be amended, abridged or displayed in a promotional manner.

13.9.2 Reference or linkages to other reputable information sources that provide valuable educational information that would enhance a member of the general public's understanding of a disease area. When making such a reference or linkage a clear screen displaying the following statements must appear before the information can be accessed:

- that the information a reader is about to be referred to may not comply with the Australian regulatory environment and that readers should refer to the CMI for products to fully understand the terms of a product's registration in Australia;
- that the intent of providing this material is informational and not as advice; and
- any information provided by this source should be discussed with the reader's healthcare professional and does not replace their advice.

13.10 Social Media

The promotion of products covered by the Code of Conduct to the general public via the Internet, including social media would breach Section 13.3 of the Code and the Commonwealth Therapeutic Goods Legislation which stipulates that prescription products must not be promoted to the public.

Information provided to the general public via any form of social media must comply with the provisions of Section 13.3, 13.4, 13.5, 13.6 and 13.8 of the Code.

All use of Social Media by Companies should comply with the following principles:

- 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 requirements and recommendations for pharmacovigilance responsibilities of sponsors of medicines* (August 2013).

13.11 Market Research with the General Public

This section deals with market research with members of the general public. It includes opinion polling, product-specific or other types of surveys. For information about market research with healthcare professionals, see Section 12.

The sole purpose of market research undertaken with the general public must be to collect data and not a means to promote to members of the general public.

When selecting individuals or organisations to undertake any market research activities, companies should ensure that the contracted organisation complies with the Australian Market and Social Research Society *Code of Professional Behaviour*, which is available at www.amsrs.com.au, or an equivalent standard of professional conduct.

13.11.1 Market research studies must be clearly identified as such when the initial approach is made to participants. It must be clear to a participant that the market research is being conducted by or on behalf of a pharmaceutical company, but the name of the particular pharmaceutical company need not be disclosed. It is recognised that the disclosure of the name of the company may bias the research.

13.11.2 Market research undertaken with patients who have been prescribed a particular prescription medicine may include specific questions about the product as long as the market research is not promotional.

13.11.3 Any payment (whether cash or voucher in lieu of cash) must be kept to a minimum and should not exceed a level commensurate with the time involved.

13.11.4 Market research should be a genuine initiative to collect relevant and useful information to enhance the quality use of medicines.

Relationship with Health Consumer Organisations and Patients

14. Relationship with Health Consumer Organisations (HCOs)

Medicines Australia recognises and supports positive and beneficial relationships between industry and health consumer organisations. Companies may enter into relationships with health consumer organisations with the objective of enhancing the quality use of medicines and supporting better health outcomes for the Australian community.

Through collaboration between Medicines Australia, the Consumers Health Forum of Australia and other health consumer organisations, a set of guidelines *Working Together – A Guide to relationships between Health Consumer Organisations and Pharmaceutical Companies* has been developed. Companies must consider these principles when entering into relationships with health consumer organisations. The guidelines and manual are available on the Medicines Australia website www.medicinesaustralia.com.au

Relationships between health consumer organisations and companies should involve the following components that are essential in any relationship:

- Respect for independence
- Achieving and maintaining public trust
- Fairness
- Openness and transparency
- Accountability

14.1 No company may request that it be the sole funder of a health consumer organisation or any of its major programs. This would not preclude a company who is the only supplier of a prescription product for a specific condition or disease from sponsoring a health consumer organisation or any of its programs.

14.2 A company must not make public use of a health consumer organisation logo or proprietary material without the health consumer organisation's agreement. In seeking such permission, the specific purpose and the way in which the logo or material will be used must be clearly stated.

14.3 A company must not seek to influence the text of health consumer organisation material in a manner favourable to its own commercial interests. This does not preclude a company from correcting factual inaccuracies.

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

The selection criteria for sponsorship to enable patients and representatives from a health consumer organisation to attend third party scientific and medical conferences must be based solely on their specific interest in a particular therapeutic area.

15.1 Where companies undertake the sponsorship of a patient or representatives from a health consumer organisation such sponsorship must:

a) be able to successfully withstand public and professional scrutiny;
b) conform to community standards of ethics and good taste; and
c) enhance the quality use of medicines.

15.2 Clear guidelines which can be publicly disclosed if required must be developed in relation to the awarding of sponsorship to a patient or representatives from a health consumer organisation.

16. Access to Company Trade Displays at Third Party Conferences

If the primary audience for a third party scientific or medical conference is healthcare professionals, it is acceptable for a pharmaceutical company to have a trade display which includes information in relation to a specific product(s). However, if the primary audience is broader than healthcare professionals, a company should carefully consider whether to purchase a trade display space or what information is made available from a trade display.

In the event that a small number of non-healthcare professionals have registered for a third party scientific conference, a company should remind staff at the trade display that they must not provide information on specific products to anyone other than a healthcare professional.

Companies hosting a trade display at a third party scientific or medical conference where non-healthcare professionals have registered to attend should request the conference organisers to include a note in the

conference program that staff at company trade displays are precluded by law, and by the Medicines Australia Code of Conduct, from giving information about specific products to non-healthcare professionals.

17. Patient Support Programs

A Patient Support Program is a company developed program that is intended to assist patients in gaining benefit from their medical treatment and to improve health outcomes and promote the quality use of medicines. Patient Support Programs may only be offered to patients who have already been prescribed a prescription-only Product. The healthcare and wellbeing of patients must be the objective of a Patient Support Program. The obligation to be open and transparent about the conduct and management of a Patient Support Program is also central. This obligation is the basis for the requirement to communicate to patients about any payments that are made to a healthcare professional in association with a Patient Support Program.

Any communication with a patient enrolled in a Patient Support Program should clearly identify the company and what materials or calls the patient may receive.

Any information provided to patients may be product specific, but must not be promotional. To ensure that such activities are not promotional, companies should note the definitions of ‘promotion’, ‘promotional’ and ‘promotional claim’ which are included in the glossary to this Code.

Companies must develop a rationale for each Patient Support Program which describes the clinical rationale for the program, the anticipated number of patients to be enrolled in the program, the type of educational/informational material to be provided to a patient, contact if any (for example phone calls, SMS, email), that may be made to a patient and the duration of the program.

A company may include information about the availability of a Patient Support Program and how to enrol in such a Program as an insert in the Product package. If an enrolment form is inserted in the Product package, there is no requirement for it to be reviewed or approved by the TGA. If a Program enrolment package insert is included, this information must not be promotional and must comply with Sections 13.3 and 13.6 of the Code. A package insert enrolment form must state that the Patient Support Program is not authorised or approved by the Australian regulator of medicines, the TGA.

Companies must ensure compliance with the following requirements if they are considering becoming involved in any Patient Support Program:

a) If a company provides or intends to provide any payment to a healthcare professional in return for any administrative or other work associated with enrolling a patient in a Patient Support Program, this payment, including the amount and scope of this payment, must be disclosed in writing to a patient prior to their enrolment in the program.
b) Any payment for the work undertaken by a healthcare professional in such programs must be commensurate with the work undertaken. Such payment should not be capable of influencing or intended to influence the prescribing or dispensing of a specific prescription product.
c) No incentives, other than material that will enhance positive health outcomes and compliance, are provided to patients to become involved in these programs.
d) Information provided to patients must inform the patient that they may opt out of the program at any time by advising the company or its nominated agent. Patients must also be advised who will be holding any details disclosed in the enrolment form and that these will not be used for purposes other than this program.
e) The program complies with Australian privacy legislation.
f) All information provided to patients must comply with Section 13 of this Code.
g) All information provided to the patient prior to their enrolment in a Patient Support Program must be balanced, accurate and correct, including information about the potential risks of the medicine.
h) The Consumer Medicine Information document for the medicine must be given to the patient prior to their enrolment or must be one of the first documents provided to a patient following their enrolment in the program.
i) The data collected from these programs must not be used for any purpose other than to increase positive health outcomes and never for promotional activities. Individual patient data may be collected in a de-identified manner for the purpose of safety monitoring. Suspected Adverse Drug Reactions noted during monitoring of a Patient Support Program must be reported to the TGA in accordance with the current TGA document *Australian requirements and recommendations for pharmacovigilance responsibilities of sponsors of medicines (August 2013).*
j) The duration of these programs is appropriate to the disease state treated by the product involved.
k) The program should not interfere in any way with healthcare professional/patient integrity.

l) Take reasonable steps to ensure that mailing or communication lists of patients enrolled in Patient Support Programs are kept up to date.

Companies can report on whether the program delivers any improvement in compliance and on the rationale for the program. However, companies may not collect data for the purpose of making a therapeutic claim about a product. This is because under a Patient Support Program data are not usually collected with the same scientific or statistical rigour as is normally expected as the basis for a product claim. However, if data is collected in a Patient Support Program using appropriate scientific and statistical rigour, under a research protocol, such data may be used to communicate to healthcare professionals. Such data may be cited as 'data on file', following the requirements of Section 1.1, and must be consistent with the body of evidence.

18. Access to Dispensary Data

No company representative may access and/or obtain data from a dispensary software system or install software or application without the informed agreement of the responsible registered pharmacist. Any data obtained must not include any personal information about patients or healthcare professionals.

19. Discredit to and Reduction of Confidence in the Industry

Activities with, or materials provided to members of the general public, health consumer organisations or patients must never be such as to bring discredit upon, or reduce confidence in the pharmaceutical industry. Such activities would be seen as a Severe Breach of the Code of Conduct.

Code Administration

The Constitution of Medicines Australia Limited, under rule 4.4, provides that each Member Company must conform to and be bound by both the Constitution and the Code of Conduct.

This Code of Conduct establishes the Code of Conduct Committee (Section 21), the Code of Conduct Appeals Committee (Section 22) and the Monitoring Committee (Section 32).

The Code of Conduct Committee (Code Committee) will consider complaints and determine whether a breach of the Code has occurred. The Code Committee may impose sanctions in accordance with Section 28 of the Code.

The Code of Conduct Appeals Committee (Appeals Committee) will consider any appeals against a determination made by the Code Committee. The Appeals Committee may affirm, set aside or vary the determination of the Code Committee and/or any sanction imposed by the Code Committee in accordance with Section 28.

In accordance with Section 29.1, the Appeals Committee shall be independent from the Code Committee in relation to hearing appeals.

Expert advice may be sought externally by the Code and Appeals Committees in reaching a decision as to whether or not a breach has occurred.

In addition to, and separately from, the powers of the Code Committee and Appeals Committee, the Board of Medicines Australia is empowered by rule 5 of the Constitution of Medicines Australia to discipline a Member Company if a Member Company is found guilty of conduct contrary to the Code of Conduct.

20. Complaints

20.1 Acceptance of Complaints

A Complainant has the burden of proving their complaint on the balance of probabilities. Anonymous complaints will not be accepted.

Medicines Australia has the discretion to either:

a) not accept a complaint; or
b) accept and delay referring a complaint to the Code Committee

where substantially the same subject matter is, at the same time, the subject of legal proceedings between the same parties in an Australian court or Administrative Tribunal.

Medicines Australia has the discretion to not accept a complaint if the subject matter has been substantially dealt with by the Code Committee.

20.2 Complaints Process and Handling

The following procedures shall apply in the event of Medicines Australia receiving a complaint alleging contravention by a company of the Code of Conduct.

20.2.1 On the receipt of a complaint, the Chief Executive of Medicines Australia or his or her delegate shall acknowledge the complaint in writing within five (5) working days of receipt. All complaints shall be dealt with as expeditiously as possible.

All documents relating to a complaint are required to be kept confidential until the complaint is deemed finalised.

The company that is the subject of the complaint (Subject Company) shall be given full details of the complaint lodged with Medicines Australia. The Subject Company will be invited to state within ten (10) working days whether or not the information supporting the complaint is correct, and to give any answer or explanation which may be deemed necessary.

The Subject Company may obtain external advice in order to respond to a Code of Conduct complaint. If external advice is sought, all documents relating to a complaint must be kept confidential and can only be provided for the purpose of seeking such advice.

If external advice is sought by a company responding to a complaint, that company must ensure that the individual to whom a request for advice is sought is provided with sufficient information to form a full and proper view of the complaint under consideration**.**

The Subject Company and Complainant will provide Medicines Australia with whatever references or information is deemed by the Chief Executive or his or her delegate to be necessary to fully investigate the complaint. The complaint and all supporting information and the Subject Company's response shall be provided to the Code Committee.

20.2.2 If the Code Committee, after making such further inquiry as is necessary or desirable, meets and reaches a decision that a breach of the Code has occurred, the Chief Executive or his or her delegate will:

a) within two (2) working days of the Committee meeting notify the Subject Company and the Complainant in writing that a breach has been found and identifying the section of the Code that the Committee has determined has been breached.
b) within ten (10) working days of the Committee meeting provide copies of the decision(s) and the reasons for the decision(s) of the Committee to the Subject Company and the Complainant which will include a full explanation for the decision made and the form of any sanction to be applied to the Subject Company, as provided for under Section 28 of the Code.

The Code Committee may also request the Code of Conduct Secretary to notify Medicines Australia's Board, and any other bodies or individuals with a direct interest, of the Committee's decision.

All findings and/or sanctions of the Code Committee shall remain confidential and shall not be released to any third party until the Subject Company and Complainant have exhausted all appeal procedures and the outcome of any appeal is known.

20.2.3 If the Code Committee requires a company to cease certain conduct or withdraw materials from use, the company shall at once comply with the Code Committee's ruling pending any appeal against the decision of the Code Committee. Conduct or materials thus suspended or withdrawn shall not be reactivated before the appeal process has been concluded.

20.2.4 If the Code Committee considers that no breach has occurred, it will so advise the Chief Executive or his or her delegate, who will so advise the parties concerned and also supply them with the decision(s) and the reasons for the decision(s) of the proceedings within ten (10) working days of the Code Committee's decision.

20.2.5 The Code Committee may refer questions on the interpretation of the Code to the Medicines Australia Board for determination. The Board shall consider such questions and make a determination as soon as possible after it receives notice from the Code Committee of the need for the determination.

21. Membership of the Code of Conduct Committee (Code Committee)

21.1 Membership

The following persons shall be eligible to be "full members" of the Code Committee:

- Chair - Lawyer with Trade Practices experience.
- One representative of the Australian Medical Association (AMA).
- One representative of the Royal Australian College of General Practitioners (RACGP).
- One representative of the Australian General Practice Network (AGPN).
- One representative of the Royal Australasian College of Physicians (RACP).
- One representative of the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT).
- One consumer representative nominated by the Consumers Health Forum of Australia (CHF). 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.
- Up to a maximum of five representatives from Medicines Australia members, drawn from the following, as relevant to the complaint:
  - Member Company Senior Executive Officers from Medicines Australia Members, as defined in Section 4.4 (6) of the Medicines Australia Constitution
  - Medical or Scientific Directors
  - Senior Compliance Officers
  - Marketing Directors

Where a complaint relates to an activity or material directed to the practice of Pharmacy, one pharmacist representative of the Pharmacy Guild of Australia (PGA), The Pharmaceutical Society of Australia (PSA) or the Society of Hospital Pharmacists (SHPA).

A properly constituted meeting of the Code Committee shall comprise not less than six full members, two of which must be representatives from Medicines Australia Member Companies and one of which must be a representative of ASCEPT. All business of the Code Committee will be conducted at a meeting of a properly constituted Code Committee.

21.2 Observers and Secretariat

In addition to the full members of the Committee, the following persons may attend a meeting of the Code Committee as observers

- One representative of the Therapeutic Goods Administration, nominated by the Therapeutic Goods Administration;
- Up to two employees of Medicines Australia Member Companies nominated by Medicines Australia who would gain an educational benefit from attendance at a Code Committee meeting and who has no conflict of interest as described in Section 24;
- One observer nominated by Medicines Australia who would gain an educational benefit from attendance at a Code Committee meeting and who has no conflict of interest as described in Section 24;
- Medicines Australia Chief Executive or delegate.

Subject to the discretion of the Chair, observers will be entitled to attend and speak at properly constituted meetings of the Code Committee.

The Code Committee will be assisted in administering the business of the Committee by a Secretariat comprising:

- The Code of Conduct Secretary; and/or
- The Medicines Australia officer responsible for the Ethical Conduct Program

Observers and members of the Code Secretariat attending a Code Committee meeting shall have no voting rights.

22. Membership of the Appeals Committee

22.1 Membership

The following persons shall be eligible to be “full members” of the Appeals Committee:

- Chair - Lawyer with Trade Practices experience.
- One representative from the College and/or Society associated with the therapeutic class of the product subject to appeal.
- One general practitioner representative of the Australian Medical Association (AMA), Royal Australian College of General Practitioners (RACGP) or Australian General Practice Network (AGPN).
- One consumer representative nominated by the Consumers Health Forum of Australia. Where an appeal is in relation to an activity or material directed at the general public or patients, a second consumer representative will be appointed.
- One representative of the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT).
- Up to a maximum of three representatives from Medicines Australia members, drawn from the following, as relevant to the complaint;
  - Member Company Senior Executive Officers from Medicines Australia Members, as defined in Section 4.4 (6) of the Medicines Australia Constitution
  - Medical or Scientific Directors
  - Senior Compliance Officers
  - Marketing Directors
- Where a complaint relates to an activity or material directed to the practice of Pharmacy, one pharmacist representative of the Pharmacy Guild of Australia (PGA), The Pharmaceutical Society of Australia (PSA) or the Society of Hospital Pharmacists (SHPA).

A properly constituted meeting of the Appeals Committee shall comprise not less than three full members, one of which must be a representative of a Medicines Australia member company. All business of the Appeals Committee will be conducted at a meeting of a properly constituted Appeals Committee.

No member of the Appeals Committee can have been a member of the Code Committee that heard the original complaint.

Medicines Australia may release to the Complainant or the Subject Company the names of the representatives nominated by the College and/or Society associated with the therapeutic class of the product or activity subject to appeal, on the condition that neither party makes contact with these experts prior to or after the Appeals Committee meeting.

22.2 Observers and Secretariat

In addition to the full members of the Appeals Committee, the following person may, at the discretion of the Chair, attend a meeting of the Appeals Committee as an observer:

- Medicines Australia Chief Executive Officer or delegate

Subject to the discretion of the Chair, an observer will be entitled to attend and speak at properly constituted meetings of the Appeals Committee.

The Appeals Committee will be assisted in administering the business of the Committee by a Secretariat comprising:

- The Code of Conduct Secretary; and/or
- The Medicines Australia officer responsible for the Ethical Conduct Program

An observer and members of the Code Secretariat attending an Appeals Committee meeting shall have no voting rights.

23 Procedure of Appointment – Code Committee and Appeals Committee

23.1 Term of Appointment

Full members of the Code of Conduct Committee and the Appeals Committee, other than the Chair, will be appointed for a period of three years and will be eligible for re-nomination at the completion of their term.

23.2 Qualifications and means of Appointment of Members

The following sets out the means of appointment and the descriptions of the persons stated in clauses 21.1 and 22.1 (to be eligible in each case as full members) that shall apply to the nominating bodies as a guide, but not as strict criteria, to the qualifications and/or experience desirable in their nominees as full members of the Code Committee or Appeals Committee, as the case may be:

Chair – a panel of up to five (5) suitably qualified and experienced lawyers will be appointed by the Medicines Australia Board. Members of the panel will be appointed to the panel for a period of five (5) years each. The Chair for a particular Code Committee or Appeals Committee meeting will be appointed from the members of the panel by the panel members, ensuring a rotation, but taking into consideration that the person has no conflict of interest as described in Section 24. The Chair for a particular Appeals Committee meeting must not have chaired the Code Committee meeting at which the original complaint was heard.

AMA Representative – a general practitioner nominated by the Australian Medical Association Ltd.

RACGP Representative – a general practitioner nominated by the Royal Australian College of General Practitioners.

AGPN Representative – a general practitioner nominated by the Australian General Practice Network.

RACP Representative – a specialist physician, to serve by rotation from a panel of three (3) specialist physicians, each nominated by the Royal Australasian College of Physicians.

ASCEPT Representative – a person to serve by rotation from a panel of four (4) persons, each nominated by the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists.

Consumer Representative(s) – a person nominated by the Consumers Health Forum of Australia

Pharmacist Representative – a person nominated by any one of the Pharmacy Guild of Australia (PGA), The Pharmaceutical Society of Australia (PSA) or the Society of Hospital Pharmacists (SHPA) at the invitation of Medicines Australia.

Medicines Australia Association Representatives, Medical/Scientific, Senior Compliance Managers and Marketing Directors – persons selected from Member Companies who have no conflict of interest with the product or company against which a complaint has been lodged as described in Section 24.

24 Conflict of Interest

In advance of each Code Committee and Appeals Committee meeting advice will be sought from the full members of the Code Committee, Appeals Committee and observers as to whether there is any conflict of interest associated with the prescription product or activity subject to complaint, the Subject Company or the Complainant.

In addition to the requirement to disclose a direct or indirect pecuniary interest in a matter about to be considered by the Code Committee or Appeals Committee, members and observers should also disclose a conflict of interest if a reasonable third party would conclude that there was a likelihood that a member of the Committee may be influenced in reaching a decision by factors other than the merits of the case as presented by the Subject Company and Complainant.

At the commencement of each Committee meeting, the Chair will again enquire as to whether any Committee member or observer has a conflict of interest associated with the prescription product or activity in relation to the complaint has been lodged, the Complainant or the Subject Company. The Code Committee or Appeals Committee, as relevant, will determine the appropriate action following this disclosure.

25. Complaints Against Non-Members

Complaints concerning the conduct of non-members will be forwarded to the non-member with an invitation to have the complaint adjudicated by the Code Committee in accordance with Section 20 and its agreement to abide by the Code Committee's decision and any sanctions imposed.

If the non-member accepts the invitation to have the complaint adjudicated by the Code Committee, the complaint will proceed in accordance with the provisions of the Code of Conduct.

If the non-member declines the invitation to have the complaint, adjudicated by the Code Committee, Medicines Australia shall have the right, but not the obligation, to forward this complaint, together with the non-member response to the invitation, to the TGA or the Australian Competition and Consumer Commission (ACCC).

26. Discretion for Referral

On receipt of a complaint which is not covered by this Code, Medicines Australia retains the discretion to refer the complaint(s) to a relevant organisation for consideration under its own Code, having regard to the category of the therapeutic good and the target audience for the conduct subject to complaint.

27. Abuse of the Code

If the Code Committee forms the view that a complaint by a company might be considered frivolous or vexatious, before the Code Committee comes to a decision it will request the Complainant Company to provide its response to the concern, including any reasoning why the Committee should not impose a fine up to of a maximum of $200,000 for abuse of the Code of Conduct. The Complainant Company's response must be provided to Medicines Australia within ten (10) working days. The Complainant Company's response will be considered at the next Code Committee meeting.

A company may be found to breach this Section if a single complaint is determined to be frivolous or vexatious or a series of complaints by a single Complainant against one or more companies within a therapeutic class.

A complaint or series of complaints may be found to be frivolous or vexatious regardless of whether or not the complaint or complaints are sustained.

28. Sanctions

Sanctions may only be imposed on a Subject Company where breaches of the Code of Conduct have been established. Under the procedures laid down in Section 20.2 of the Code, Sanctions may consist of one or more of the following:

- Cessation of conduct and withdrawal (Section 28.1);
- Corrective action (Section 28.2); and/or
- Monetary fine (Section 28.3).

In the event that Code Committee requires a company to cease conduct, withdraw promotional materials, send a corrective letter or place corrective advertising, or pay a monetary fine, the company shall at once comply with the Code Committee's ruling pending any appeal against the decision of the Code Committee. Any activity or promotional material thus suspended shall not be reactivated or recommenced before the appeal process has been concluded.

28.1 Cessation of Conduct and Withdrawal of Promotional Activity

A requirement for the Subject Company to take immediate action to discontinue or modify any conduct which is determined to constitute a breach of the Code, including the cessation and withdrawal of any promotional activity. Written notification of this action must be provided to Medicines Australia within five (5) working days of the receipt of the decision(s) and the reasons for the decision(s) of the Code Committee.

Where a company fails to cease an activity or withdraw promotional materials, Medicines Australia shall have the right, but not the obligation:

i. to forward the complaint, the decision(s) and the reasons for the decision(s) of the Code or Appeals Committee meeting, and the failure of the Subject Company to take the corrective action, to the TGA or the ACCC; and/or
ii. publicise the failure of the Subject Company to take the corrective action.

28.2 Corrective Action

A requirement for retraction statements, including corrective letters and advertising, to be issued by the Subject Company.

The number, format, size, wording, mode of publication, prominence, timing (including duration of publication) and method of distribution of corrective statements must be approved by the Committee or its delegates prior to release.

Corrective statements will, in general, specifically correct the statement found in breach of the Code and, if the Committee has prescribed the form of such statements, be in the form prescribed. No other material may accompany such statements unless the inclusion of such material has been approved by the Committee or its delegates.

As a general rule, there will be a requirement for corrective action to be taken where Moderate or Severe breaches have been found.

Any corrective statement or letter required by the Code Committee should be mailed in an envelope that states on the front surface 'Company X Corrective Letter'.

It will be usual for the Code Committee to require that a statement informing readers of the availability of the Code of Conduct will be made in corrective letters and advertising.

The corrective statement or letter must not make reference to the identity of the Complainant.

It is the Subject Company's responsibility to ensure that the requirements of the Committee or its delegate are met and to immediately inform and provide evidence to Medicines Australia of their fulfilment.

Any corrective action required by the Code Committee must be completed within 30 calendar days of the receipt of the decision(s) and the reasons for the decision(s) of the Code Committee meeting by the Subject Company (subject to any appeal that may be lodged under Section 29 of the Code).

A Subject Company is required to provide a statement to the effect that the action has been undertaken together with a copy of the published advertisement or a copy of the final version of a corrective letter, signed by the Subject Company Managing Director or Medical Director.

Where corrective action has not been actioned within 30 calendar days from receipt of the decision(s) and the reasons for the decision(s) of the Code or Appeals Committee meeting, the Code Committee may impose a fine of up to $50,000 for that breach of not actioning the corrective action.

In addition, Medicines Australia shall have the right, but not the obligation:

i. to forward the complaint, the decision(s) and the reasons for the decision(s) of the Code or Appeals Committee meeting, and the failure of the Subject Company to take the corrective action to the TGA or the ACCC; and/or
ii. publicise the failure of the Subject Company to take the corrective action.

28.3 Monetary Fines

The imposition of a monetary fine on the Subject Company in accordance with the schedule of fines below.

The monetary fine must be paid within 30 calendar days from receipt of the decision(s) and the reasons for the decision(s) of the Code Committee meeting subject to any appeal that may be lodged under Section 29 of the Code.

Where a monetary fine has not been paid within the required 30 calendar days from receipt of the decision(s) and the reasons for the decision(s) of the Code or Appeals Committee meeting, the Code Committee may impose a further fine of up to $50,000 for that breach of not paying the fine within the required period.

In addition, Medicines Australia shall have the right, but not the obligation:

i. to forward the complaint, the decision(s) and the reasons for the decision(s) of the Code or Appeals Committee meeting, and the failure of the Subject Company to pay the fine within the required period to the TGA or the ACCC; and/or
ii. publicise the failure of the Subject Company to pay the fine.

The schedule of fines that may be imposed by the Committee for breaches of the Code of Conduct is as follows. A range of fines is available to the Committee.

Breach	**Fine**
Technical	Maximum $100,000
Minor	Maximum $100,000
Moderate	Maximum $150,000
Severe	Maximum $200,000
Severe Breach where the activity has been completed before a breach found and no opportunity for corrective action	Maximum $250,000
Repeat of Previous Breach	Maximum $250,000
Failure to complete corrective action in 30 calendar days	Maximum $50,000
Failure to pay a fine in 30 calendar days	Maximum $50,000
Abuse of the Code (in accordance with Section 25)	Maximum $200,000

The Code Committee and the Appeals Committee have the discretion to apply a monetary fine for breaches of the Code individually or cumulatively. The fines above may be imposed for each identified breach determined under Section 20 of the Code up to a maximum of $300,000 per complaint. By way of example, if a moderate breach and a severe breach were determined within one complaint, the Committee may impose a fine of up to $300,000.

29. Appeals

29.1 Appeal Procedures

The following procedures shall apply if Medicines Australia receives an appeal from a Complainant or Subject Company concerning a decision of the Code of Conduct Committee. The appeal will be heard by the Code of Conduct Appeals Committee (Appeals Committee).

An appeal is a rehearing of the original complaint. The Appeals Committee has the power to affirm, set aside or vary the findings and/or any sanction which has been imposed by the Code Committee. The Appeals Committee shall not uphold an appeal unless it is persuaded that the findings of the Code Committee or the sanction imposed by it, involved an error on the basis of which they should be set aside or varied.

The Appeals Committee will determine the appeal on the basis of the evidence before the Code Committee, the submissions made to that Committee, and the submissions made to the Appeals Committee. The Appeals Committee shall have the discretion to receive fresh evidence (being evidence which has become available after the complaint was considered by the Code Committee). However, the Appeals Committee will make its determination in relation to the circumstances that existed at the time the conduct or activity occurred, not the circumstances existing at the time of the Code of Conduct Committee's deliberation or at the appeal. For example, the Appeals Committee will have regard only to what substantiating clinical evidence was published and available at the time a claim subject to complaint was made.

The appeal is to be dealt with during a meeting of the Appeals Committee. Both the Subject Company and the Complainant may provide an oral presentation to the Appeals Committee.

Where a company enlists the assistance of an external expert, the expert shall not act as an advocate for the company's conduct or activities.

All documents relating to a Code of Conduct Appeal are required to be kept confidential until the appeal is finalised (See Appendix 1).

29.1.1 A Subject Company that has been found in breach of the Code and had a sanction imposed under Section 20 of the Code may lodge an appeal against the findings and/or sanction that has been imposed. Notice of an appeal must be made in writing by the Subject Company within five (5) working days of receiving the decision(s) and the reasons for the decision(s) of the Code of Conduct Committee. The Notice must be addressed to the Secretary of the Code of Conduct Committee. On receipt of a Notice of appeal, the Complainant will be notified and provided with a copy of the Subject Company's response to the complaint.

The Subject Company must submit its written submissions in support of its appeal to Medicines Australia within a further five (5) working days. The written appeal will be provided to the Complainant which shall make its written response to the appeal within five (5) working days. The written appeal submission and any response to the appeal shall be provided to the Appeals Committee.

The Complainant's response to the appeal will be provided to the Subject Company for its review prior to the Appeals Committee meeting.

29.1.2 A Complainant may lodge an appeal in relation to the findings of the Code Committee. Notice of an appeal by the Complainant must be made in writing within five (5) working days of receiving the decision(s) and the reasons for the decision(s) of the Code of Conduct Committee. The Notice of appeal shall be addressed to the Secretary of the Code of Conduct Committee. On receipt of an appeal by the Complainant, the Subject Company will be notified.

The Complainant will be given five (5) working days to prepare a written submission in support of its appeal. The written appeal will be provided to the Subject Company which shall submit to Medicines Australia its written response to the appeal within five (5) working days of receipt of the appeal submission.

The written appeal submission and any response to the appeal shall be provided to the Appeals Committee.

The Subject Company's response will be provided to the Complainant for review prior to the Appeals Committee meeting.

All documents relating to a complaint and appeal shall remain confidential and shall not be released to any third parties until after the Subject Company and Complainant have exhausted all appeal procedures and the outcome of any appeal is known.

29.1.3 When a Subject Company or industry Complainant submits an appeal in accordance with Section 29 of the Code, the company must lodge a bond of $20,000 with Medicines Australia. A non-industry Complainant will not be required to lodge an appeal bond if it lodges an appeal against the Subject Company. The Appeals Committee has the discretion to refund all, part or none of the $20,000 bond in the event of the findings and/or the sanction being removed or changed. This bond will be retained by Medicines Australia to defray the costs of the Code and Appeals Committee meetings and contribute to Code education programs.

There shall be only one bond of $20,000 payable by an industry appellant for each complaint, irrespective of the number of findings of a breach(es) or sanctions imposed.

29.1.4 In the event of an appeal being lodged by the Subject Company and the Complainant in relation to a single complaint, both appeals will be heard concurrently by the Appeals Committee.

The Appeals Committee has the discretion to require that a single bond of $20,000 be lodged with Medicines Australia if more than one appeal is submitted at the same time and in relation to the same or closely similar conduct which can be dealt with at the one Appeals Committee meeting.

29.1.5 Twelve (12) copies of an appeal submission from the Subject Company or Complainant must be provided to Medicines Australia.

29.1.6 Twelve (12) copies of a response to an appeal from the Subject Company or Complainant must be provided to Medicines Australia.

29.1.7 A Complainant company that has had fines imposed by the Code Committee under Section 27 (Abuse of the Code) may lodge an appeal against the fine. The appeal, in writing, must be submitted to Medicines Australia by the Complainant within five (5) working days of receiving advice of the fine, addressed to the Secretary of the Code of Conduct Committee. This appeal will be determined by the Medicines Australia Board.

30. Referral to Medicines Australia Board

The Appeals Committee may refer questions on the interpretation of the Code to the Medicines Australia Board for determination. The Board shall consider such questions and make a determination as soon as possible after it receives notice from the relevant Committee of the need for the determination.

Monitoring

31. Monitoring

31.1 General Principles

To promote compliance with the Medicines Australia Code of Conduct and thereby support the quality use of medicines, the Medicines Australia Monitoring Committee (Monitoring Committee) will proactively monitor selected promotional material and conduct of Member Companies on a regular and ongoing basis.

The aims of monitoring are to encourage compliance with the Code of Conduct, provide advice on compliance where necessary, obtain and publish statistical data on the degree of compliance and to provide an ongoing mechanism for the identification of potential future amendments to the Code of Conduct.

The Monitoring Committee may review any form of promotional material and any conduct governed by the Code for identified therapeutic classes against the provisions of this Code.

31.2 Monitoring Procedures

31.2.1 Review of promotional materials and activities

Monitoring Committee reviews cover two areas:

a) Promotional materials, which are reviewed within specific therapeutic areas. These include:
   - Printed promotional materials, including detail aids and 'leave behinds'
   - Advertisements in print media
   - Advertisements in electronic and/or audio-visual media, including electronic detail aids and advertisements in eNewsletters

The review of promotional materials will be within one or more of the following Therapeutic Classes:

- Alimentary System
- Analgesia
- Cardiovascular System
- Central Nervous System
- Contraceptive Agents
- Ear, Nose and Oropharynx
- Endocrine and Metabolic Disorders
- Eye
- Genito-urinary System
- Immunology
- Infections and Infestations
- Musculoskeletal System
- Neoplastic Disorders
- Respiratory System
- Skin

b) activities conducted by most companies, which are not restricted to specific therapeutic areas. These include:
   - Company websites available to the general public
   - Market research
   - Educational meetings and symposia
   - Support for Health Consumer Organisations
   - Payments to healthcare professional consultants and Advisory Board members
   - Supply of starter packs
   - Product Familiarisation Programs
   - Websites with access restricted to healthcare professionals
   - Patient support materials
   - Patient aids
   - Disease education materials for the general public
   - Company policies and procedures to ensure compliance with Medical Representative training
   - Company policies and procedures to ensure that educational events for healthcare professionals comply with the Code

In a financial year the Monitoring Committee will conduct a minimum of three reviews of promotional materials, each within one or more therapeutic classes specified by the Medicines Australia Code Secretariat, and a minimum of three reviews of different activities described under point b) above, which will be across all therapeutic classes.

Member Companies will be required to submit to the Committee ten (10) copies of the selected type of promotional material or other material that was in use during a specified three month period.

It is acknowledged that although the Monitoring Committee has the right to request all types of promotional or other material during a review, companies will only be required to submit materials of the type specified by the Medicines Australia Code Secretariat. For example, the Committee may review printed advertisements for a specific therapeutic class in one review and at their next meeting review audio-visual material for products in a different therapeutic class.

The Monitoring Committee is empowered in any case to request, and Member Companies must provide, any further information concerning a particular advertisement, item of printed promotional material or activity such as supporting references, a program for an educational meeting, or documentation to support payments associated with an activity.

A Member Company will only be required to provide promotional materials or information associated with other activities for review by the Monitoring Committee on no more than three occasions within a calendar year. If a Member Company responds to a Monitoring Committee request that it had not distributed any promotional materials or undertaken any activities that are specified in the request, this response will not be counted as one of the three occasions for that company.

However, in accordance with Section 31.2.2, a Member Company will nevertheless be required to respond to a request from the Monitoring Committee for further information concerning a particular educational meeting, Advisory Board meeting, Health Consumer Organisation support or consultancy arrangement. That is, notwithstanding that a Member Company might have already submitted its materials for review on three occasions during the calendar year, if it receives a request from the Monitoring Committee for further information relating to an educational meeting, Advisory Board or consulting arrangement or Health Consumer Organisation support, it must provide the information requested to the Monitoring Committee.

31.2.2 Review of educational meetings and symposia

In addition to the review of promotional materials and activities described in Section 31.2.1, the Monitoring Committee will, at the end of each financial year, review the educational meetings and symposia provided by Member Companies in accordance with Section 41.2.2 and 41.3.5 of the Code. The review will be of information about educational meetings held during three months selected by the Committee at random.

The Monitoring Committee is empowered in any case to request, and Member Companies must provide, any further information concerning a particular educational meeting such as a copy of the invitation to the meeting, agenda, program, a copy of any materials provided to attendees and invoices and receipts.

31.2.3 Verification

A written statement, signed by the Medicines Australia Member, as defined in Section 4.4 (6) of the Medicines Australia Constitution confirming that the information supplied to the Monitoring Committee is a true record and constitutes all the requested materials, will be required.

32. Membership of the Monitoring Committee

32.1 Membership

The following persons shall be eligible to be "full members" of the Monitoring Committee:

- Chair – a consultant with industry experience in marketing and knowledge of the Code of Conduct
- One representative of the Royal Australian College of General Practitioners (RACGP)
- One representative of the Australian Medical Association (AMA)
- One consumer representative of the Consumers Health Forum of Australia. Where the review is in relation to an activity or material directed at the general public or patients, a second consumer representative will be appointed.

Rotating Members

- One representative of the College and/or Society associated with the therapeutic class being reviewed
- Up to a maximum of two representatives from Medicines Australia members, drawn from, as relevant to the materials or activities being reviewed by the Monitoring Committee, the following:
  - Medical or Scientific Directors
  - Marketing Directors
  - Senior Compliance Officers

A properly constituted meeting of the Monitoring Committee shall comprise not less than three full members, one of which must be a representative of a Medicines Australia member company and one of which must be a representative of the Consumers Health Forum. All business of the Monitoring Committee will be conducted at a meeting of a properly constituted Monitoring Committee.

32.2 Observers and Secretariat

In addition to the full and rotating members of the Monitoring Committee, the following persons may attend a meeting of the Monitoring Committee as observers:

- Up to two employees of Medicines Australia Member Companies nominated by Medicines Australia who would gain an educational benefit from attendance at a Monitoring Committee meeting and who has no conflict of interest as described in Section 34;
- One observer nominated by Medicines Australia who would gain an educational benefit from attendance at a Monitoring Committee meeting and who has no conflicts of interest as described in Section 34;
- Medicines Australia Chief Executive or delegate.

Subject to the discretion of the Chair, observers will be entitled to attend and speak at properly constituted meetings of the Monitoring Committee.

The Monitoring Committee will be assisted in administering the business of the Committee by a Secretariat comprising:

- The Code of Conduct Secretary; and/or
- The Medicines Australia officer responsible for the Ethical Conduct Program

Observers and members of the Code Secretariat attending a Monitoring Committee meeting shall have no voting rights.

33 Procedure of Appointment – Monitoring Committee

33.1 Term of Appointment

Full members of Monitoring Committee, other than the Chair, will be appointed for a period of three years and will be eligible for re-nomination at the completion of their term.

33.2 Qualifications and means of Appointment of Members

The following sets out the means of appointment and the descriptions of the persons stated in clauses 32.1 (to be eligible in each case as full members) that shall apply to the nominating bodies as a guide, but not as strict criteria, to the qualifications and/or experience desirable in their nominees as full members of the Monitoring Committee:

Chair – a panel of up to three (3) suitably qualified and experienced consultants will be appointed by the Medicines Australia Board. Members of the panel will be appointed to the panel for a period of five (5) years each. The Chair for a particular Monitoring Committee meeting will be appointed from the members of the panel by the panel members, ensuring a rotation, but taking into consideration that the person has no conflict of interest as described in Section 34.

AMA Representative – a general practitioner nominated by the Australian Medical Association Ltd.

RACGP Representative – a general practitioner nominated by the Royal Australian College of General Practitioners.

Consumer Representative – a person nominated by the Consumers Health Forum of Australia

34 Conflict of Interest

In advance of each Monitoring Committee meeting advice will be sought from full members and observers of the Committee as to whether there is any conflict of interest associated with either the therapeutic class subject to review or the companies that have submitted materials for review.

In addition to the requirement to disclose a direct or indirect pecuniary interest in a matter about to be considered by the Monitoring Committee, members and observers should also disclose a conflict of interest if a reasonable third party would conclude that there was a likelihood that a member of the Monitoring Committee may be influenced in reaching a decision by factors other than the merits of the case.

At the commencement of the Monitoring Committee meeting the Chairman will again enquire as to whether any Committee member or observer has a conflict of interest associated with the therapeutic class subject to review or the companies that have submitted materials for review. The Committee will determine the appropriate action following this disclosure.

35. Referral to the Code of Conduct Committee

If, following the review of the submitted material or activities, the Monitoring Committee considers that a breach of the Code of Conduct may have occurred, the company in question will be contacted and asked to state whether the determination of the Monitoring Committee is correct and to give any answer or explanation deemed necessary.

The Monitoring Committee will consider the company's response and provide relevant advice on compliance with the Code or, if necessary, refer the matter to the Code Committee as a complaint.

Where the Monitoring Committee considers the conduct of the Member Company with regard to an educational meeting reported to Medicines Australia in accordance with Section 37.4 of the Code may breach the Code of Conduct, the Committee will refer a report about the meeting and the Member Company's response to the Code of Conduct Committee which, after giving notice to the Member Company, may deal with it as if it were a complaint.

36. Monitoring Committee Reporting

The Monitoring Committee will contribute to the Medicines Australia Code of Conduct Annual Report. This report will include the therapeutic classes and type of promotional materials reviewed in the preceding twelve months, the number of items reviewed, the number and type of breaches detected and the number of Code of Conduct complaints generated.

In addition, the Monitoring Committee will provide a report to Medicines Australia of any issues concerning the Code of Conduct that may require review or amendment.

37. Review of the Monitoring Committee

The operations of the Monitoring Committee will be reviewed in association with each review of the Code.

Reporting, Review and Compliance

38. Review of the Code

Medicines Australia will conduct a review of the provisions of the Code of Conduct, seeking input from interested parties, no later than every three years.

39. Company Compliance Procedures

It is the responsibility of all companies to ensure that an internal compliance procedure exists that strives for compliance with all provisions of the Code and the spirit it embodies. This procedure should be documented and provided to relevant employees to further enhance Code of Conduct compliance.

40. Medicines Australia Reporting

40.1 Annual Report

Medicines Australia will issue an Annual Report on the activities of the Code of Conduct, Appeals and Monitoring Committees that will be available to the industry, members of the healthcare professions and general public. The Code of Conduct Annual Report will contain the following information regarding complaints considered by the Code and Appeals Committees during the reporting year:

a) names of companies that have had complaints brought against them;
b) the name of the Complainant, unless their identity has been suppressed at the request of the Complainant;
c) the product, behaviour, conduct and/or promotional material subject to the complaint;
d) a summary of the complaint, response and deliberations of the Code of Conduct and Appeals Committees;
e) the Section(s) of the Code, if any, which was breached and the reasons for finding the breach;
f) any sanctions imposed for the breach(es);
g) the total number of complaints received and the totals from the various segments of the industry;
h) the total number of breaches found;
i) a record of attendance of the representatives of independent organisations at Code Committee meetings; and
j) performance indicators as to the time taken to deal with complaints and activities undertaken to increase healthcare professional's awareness, agencies working for the industry and members of the general public of the Code of Conduct.

All of the information mentioned in paragraphs (a) to (f) above shall remain confidential and shall not be included in the Code of Conduct Annual Report until after the exhaustion of all appeals procedures and the outcome of any appeal is made known to the Complainant and Subject Company.

The Code of Conduct Annual Report will also contain a detailed report on the reviews conducted by the Monitoring Committee. This report will also list any complaints forwarded to the Code of Conduct Committee setting out the name of the Member Company and the date it was referred.

40.2 Quarterly Reports

In addition to the Annual Report, Medicines Australia will publish a quarterly report on the outcomes of all complaints finalised during the reporting period. This report will be available on the Medicines Australia website.

Reports will include the following information:

a) the name of the company against which a complaint has been made;
b) the name of the Complainant, unless their identity has been suppressed at the request of the Complainant and with the agreement of the Code of Conduct Committee Chairman;
c) the product, behaviour, conduct and/or promotional material subject to the complaint;
d) a summary of the complaint, response and deliberations of the Code and Appeals Committee;
e) the section(s) of the Code, if any, which was breached and the reasons for finding the breach(es); and
f) any sanctions imposed for the breach.

The disclosure of this information will not occur until after the exhaustion of all appeals procedures and the outcome of any appeal is known.

40.3 Complaints where the Activity was Directed Towards the General Public

Information regarding complaints that involve activities directed towards members of the general public will be made available on the Medicines Australia website within one month of finalisation of the complaint.

Reports will include the following information:

a) the name of the company against which a complaint has been made;
b) the name of the Complainant, unless their identity has been suppressed at the request of the Complainant and with the agreement of the Code of Conduct Committee Chairman;
c) the product, behaviour, conduct and/or promotional material subject to the complaint;
d) a summary of the complaint, response and deliberations of the Code and Appeals Committee;
e) the section(s) of the Code, if any, which was breached and the reasons for finding the breach(es); and
f) any sanctions imposed for the breach.

The disclosure of this information will not occur until after the exhaustion of all appeals procedures and the outcome of any appeal is known.

41. Transparency Reporting

Transparency is a cornerstone in fostering trust between government, industry, healthcare professionals and patients.

In Edition 18 of the Code the reporting requirements for Health Consumer Organisation support remain unchanged.

For all other types of reporting, the reporting requirements will follow those of Edition 17 until 30 September 2015. From 1 October 2015 the enhanced transparency reports come into effect, providing greater transparency on important interactions between Member Companies and Australian healthcare professionals.

The move transitions from reporting in an aggregated manner to the enhanced transparency reporting of transfers of value for key activities. These key activities were identified after full and careful consideration and with due regard to the Privacy Amendment (Enhancing Privacy Protection) Act 2012 (Cth). A guiding principle was to provide the most meaningful and significant disclosure achievable within the timeframe of Edition 18 of the Code.

Companies are only required to report payments or other transfers of value that are related to prescription medicines. Companies that have separate operating divisions that do not supply prescription medicines for human use (for example, animal health divisions) are only required under this Code to report payments to healthcare professionals related to prescription medicines.

41.1 Reporting of Health Consumer Organisation Support

Continuing from Section 14.4 of Edition 17 of the Code and for the duration of Edition 18 of the Code, each company must provide to Medicines Australia for publication on its website, a report listing health consumer organisations to which it provides financial support and/or significant direct/indirect non-financial support. The published report must follow the table format provided in Appendix 6 and must include:

a) the name of the health consumer organisation; and
b) a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the nature of the support; and
c) the monetary value of financial support and of invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value, the published information must describe clearly the non-monetary value that the organisation receives.

The report must be provided to Medicines Australia on an annual basis by 30 April each year covering the previous calendar year.

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

It is the responsibility of a company to inform a health consumer organisation that any sponsorship received by the health consumer organisation from the pharmaceutical company, whether sponsorship of the

organisation, a specific publication, website or activity, and including the monetary value of the sponsorship, will be publicly disclosed.

41.2 Reporting for activities conducted from 1 January 2015 to 30 September 2015

Relevant activities that occur up until 30 September 2015 must be reported in accordance with the following requirements.

41.2.1 Reporting Payments to Healthcare Professional Consultants and Advisory Board Members

Continuing from Section 9.10 of Edition 17 of the Code, for activities conducted from 1 January 2015 to 30 September 2015, companies must provide to Medicines Australia for publication on its website aggregate details of the fees paid by them to healthcare professional consultants in Australia, and/or to their employers on their behalf, for certain services rendered by them.

This includes, but is not limited to, all consultancy services provided in relation to education meetings, preparation of promotional materials or product position papers, chairing and speaking at educational meetings, assistance with training and participation in advisory boards or other therapy advice.

This does not include payments to consultants in relation to research and development work, including the conduct of clinical trials.

The public disclosure of aggregate transfers of value to Consultants and Advisory Board members includes all payments in respect of

- Consultancy fee, sitting fee, honoraria, chair person's fee or similar;
- Hospitality;
- accommodation (both within and outside Australia); and
- any travel undertaken within or outside Australia

where the hospitality, travel and accommodation was associated with the provision of the consulting or Advisory Board services.

Fees, hospitality, travel and accommodation costs in relation to Section 41.3.1 must be declared whether paid directly to healthcare professionals or to their employers or to other third party organisations companies (e.g. charities).

Each Member Company will provide a report to Medicines Australia detailing all transfers of value made to healthcare professional consultants and Advisory Board members:

a) by completing the tables as set out in Appendices 4 and 5
b) by providing a copy of the completed tables to Medicines Australia within the time frames stated below.

<u>Consultancies Report</u>

The completed table for consultancies, excluding Advisory Boards, must include the total number of consultancies per annum, total cost of consultancy fees, total number of consultants and total costs of any hospitality, accommodation (both inside and outside Australia) and travel. The names of the consultants need not be disclosed.

The report for 2014 is for the calendar year and must be submitted to Medicines Australia by 30 April 2015. The last required report is for the period covering 1 January 2015 to 30 September 2015 and must be submitted to Medicines Australia by 31 January 2016.

<u>Advisory Boards Report</u>

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

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

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

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

41.2.2 Reporting of Educational Events

Continuing from Section 37.4 of Edition 17 of the Code, for activities conducted from 1 January 2015 to 30 September 2015, each Member Company will provide a report to Medicines Australia on all educational meetings and symposia as defined in Section 9 of the Code held or sponsored by that company:

a) by completing the table as set out at Appendix 3 of the Code for each month of the financial year until 30 September 2015, and
b) by providing a copy of the completed table for two six-month periods (October 2014 – March 2015 and April 2015 - September 2015) to Medicines Australia within 30 days of the end of each six-month period.

The completed table must also include:

i. Details of sponsorships of healthcare professionals or non-healthcare professionals to attend any educational event. Sponsorship in this context includes registration fees, costs of accommodation (both inside and outside Australia) and travel related expenses.

   The information which must be disclosed is the total amount paid for each educational event or meeting in respect of all recipients of sponsorship and the total number of recipients. The names of the recipients need not be disclosed.

ii. Details of any payments to speakers to attend and give a presentation at an educational meeting. The details of payments for speakers include any fees, registration costs, costs of accommodation (both within and outside Australia) and travel related expenses.

   The information which must be disclosed is the total amount paid in fees to speakers for each educational event or meeting in respect of all speakers and the total number of speakers receiving payment. The names of the recipients need not be disclosed.

Medicines Australia will make publicly available on its website the completed tables provided by each Member Company as required by this Section within three months of the end of each six-month period.

The information disclosed in accordance with Section 41.2.2 must remain in the public domain for at least three years from the date of publication.

From 1 October 2015 the reporting requirements set out under Section 41.3.5 apply and hospitality must comply with the monetary limit stated in Section 9.4.3.

41.3 Transparency Reports for activities conducted from 1 October 2015

Transparency reporting is a public benefit to provide visibility for consumers of payments and transfers of value to healthcare professionals who are engaged in patient care.

Healthcare professionals provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and management experience. This expertise contributes towards quality use of medicines and improved patient care. It is reasonable for healthcare professionals to be fairly compensated for legitimate expertise and services provided to the industry, and that such compensation be publicly disclosed by the pharmaceutical industry.

The pharmaceutical industry also contributes to the quality use of medicines in Australia through the provision of education and sponsorship and support of healthcare professionals to attend educational and scientific meetings. Community expectations will be addressed by the enhanced public disclosure of these interactions.

The intention of transparency is not to capture or report payments or transfers of value to healthcare professionals that arise through employment by a Member Company.

Each company must report on its own website the reports described under Section 41.3.1. The initial reports covering the period 1 October 2015 to 30 April 2016 must be published on companies' websites by 31 August 2016 and every 6 months thereafter. Companies are required to report transfers of value in the following formats:

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

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

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

The most senior executive officer of the company will provide to Medicines Australia a signed and dated declaration that it has published the required report on the company's website and that the report includes all payments and transfers of value required under Section 41.3.1. This declaration must be provided to Medicines Australia within seven calendar days following publication of each report.

41.3.1 Reporting of Transfers of Value to Healthcare Professionals.

From 1 October 2015, transfers of value to Healthcare Professionals that must be reported are:

- Fees paid to healthcare professionals in return for speaking at an educational meeting or event.
- Sponsorship of a healthcare professional to attend an educational event in accordance with Section 9.7
  - Specific reportable items in regard to sponsorships are any airfare, accommodation or registration fees directly associated with the meeting (whether held within or outside Australia).
- Fees paid to healthcare professional consultants in Australia, or to their employers on their behalf, for specific services rendered by them. This includes, but is not limited to all consultancy services provided in relation to educational meetings, preparation of promotional materials or product position papers, assistance with training or any other advice to the company. This does not include payments to consultants in relation to research and development work, including the conduct of clinical trials.
  - Specific reportable items include all payments in respect to consulting fees, accommodation and airfares (both within and outside Australia) associated with the provision of the consulting services
- Fees paid to healthcare professionals in their role as Advisory Board members in accordance with Section 9.9.
  - Specific reportable items include all payments in respect to Advisory Board sitting fees, accommodation and airfares (both within and outside Australia) associated with the activities of the Advisory Board.
- Fees paid to healthcare professionals for the purpose of market research
  - Such fees will be reportable for the individual healthcare professional where the identity of the healthcare professional is known to the company.
  - Reporting is not required where the company contracting the market research is not involved in the selection of participating healthcare professionals and is not aware of the identities of those participating in the market research.

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

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

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

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

Reporting of all individual transfers of value for each healthcare professional is required, indicating the following information:

- date of the event or provision of service;
- healthcare professional's name;
- type of healthcare professional (i.e. medical practitioner, pharmacist, nurse practitioner);
- healthcare professional's principal practice address;
- description of the service (i.e. speaker, Advisory Board member, Chairperson at educational meeting etc.);
- description of the event (i.e. company sponsored meeting in Australia; independent meeting held in Australia; independent meeting held overseas; etc.);
- whether the payment was made to the healthcare professional or a third party;
- the amount of the payment or transfer of value, subdivided into (where relevant) registration fees, travel and accommodation, and fees for service.

41.3.2 Informed Consent

Companies must comply with Australian Privacy legislation (Privacy Act 1988 (Cth)) in regard to the reporting of individual healthcare professional data. Each company must establish a means to ensure informed consent and maintenance of records which comply with Australian Privacy legislation.

Where recipients of transfers of value cannot be identified for legal reasons, the amount attributable to such transfers must be reported on an aggregate basis by each company. The number of recipients involved must be stated and the aggregate amount attributable to transfers of value to such recipients.

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

41.3.2 Requirements for Making and Reporting Transfers of Value to Healthcare Professionals

Companies must comply with Australian Privacy legislation (Privacy Act 1988 (Cth)) in regard to the reporting of individual healthcare professional data. Each company must establish a means to ensure maintenance of records which comply with Australian Privacy legislation.

Companies must not make a transfer of value of a kind referred to in Section 41.3.1 unless they have taken appropriate steps to give notice of this disclosure obligation, so that the healthcare professional would reasonably expect the disclosure.

41.3.3 Validation

Companies will provide healthcare professionals for whom they have collected information about payments and transfers of value the opportunity to review and submit corrections to the information. The period provided for review and verification or correction must be at least six weeks.

41.3.4 Period of public disclosure of reports and retention of records

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

41.3.5 Reporting of Sponsorship of Third Party Educational Meetings and Symposia

From 1 October 2015 the following requirements will apply to the reporting of companies' sponsorship of educational meetings and symposia organised by third party organisations.

Each Member Company will provide a report to Medicines Australia on all sponsorships of independent educational meetings and symposia, as defined in Section 9.5 of the Code:

a) by completing the table as set out in the Code of Conduct Guidelines, for each six-month period 1 November – 30 April and 1 May – 31 October, and
b) by providing a copy of the completed table to Medicines Australia within four months from the end of each six-month period.

Each company's report submitted in accordance with Section 41.3.5 for the initial period covering the seven months from 1 October 2015 to 30 April 2016 must be submitted to Medicines Australia by 31 August 2016 for publication. Thereafter the reports will each cover a six-month period following the periods described in 41.3.5 a) and b) above.

Medicines Australia will make publicly available on its website the completed reports provided by each Member Company within two months of the date on which the reports must be submitted to Medicines Australia.

The following are examples of sponsorships of independent educational events that must be reported:

- financial sponsorship of a third party educational event;
- monetary contribution to support the conduct of grand rounds, clinic meetings or journal club meetings;
- purchase space for providing a trade display at an educational event (including if this is the only sponsorship of the event).

If a company only directly provides hospitality (food and beverages) for an educational meeting, that is the company brings in sandwiches and drinks or similar modest hospitality, this is not reportable. However, the hospitality must comply with the requirements of Section 9.4.3.

41.4 Summary of changes to reporting

Report type	Period the Report Covers	Report Published by	Date Report submitted (if to MA)	Date Report published
Health Consumer Organisation Support Report *(Ongoing)*	1 Jan – 31 Dec every year	Medicines Australia	30 April every year	30 June every year
Healthcare Professional Consultants Report *(until 30 Sept 2015)*	1 Jan 2015 – 30 Sept 2015	Medicines Australia	31 Jan 2016	31 March 2016
Advisory Board Meeting Report *(until 30 Sept 2015)*	1 Oct 2014 – 31 March 2015	Medicines Australia	30 April 2015	30 June 2015
	1 April 2015 – 30 Sept 2015	Medicines Australia	30 Oct 2015	31 Dec 2015
Educational Event Reports *(until 30 Sep 2015)*	1 Oct 2014 – 31 March 2015	Medicines Australia	30 April 2015	30 June 2015
	1 April 2015 – 30 Sept 2015	Medicines Australia	30 Oct 2015	31 Dec 2015
NEW Healthcare Professionals Report *(from 1 Oct 2015)*	1 October 2015 – 30 April 2016	Company websites		31 Aug 2016
	1 May 2016 – 31 October 2016	Company websites		28 Feb 2017
	1 Nov 2016 – 30 April 2017	Company websites		31 Aug 2017
NEW Report Sponsorship of Third Party Educational Events Report *(from 1 Oct 2015)*	1 October 2015 – 30 April 2016	Medicines Australia	31 Aug 2016	31 Oct 2016
	1 May 2016 – 31 October 2016	Medicines Australia	28 Feb 2017	30 April 2017
	1 Nov 2016 – 30 April 2017	Medicines Australia	31 Aug 2017	31 Oct 2017

Detailed guidelines for Lodging a complaint by a non-industry complainant, and guidelines for Lodging and responding to a complaint for pharmaceutical Companies, can be found on the Medicines Australia website at www.medicinesaustralia.com.au.

These guidelines are intended to assist both the Complainant and Subject Company to ensure that a fair and full review is conducted.

If these general criteria are not met, the complaint may be returned for more information, or the review may be conducted in the absence of a complete response.

Non-industry Generated Complaints

A non-industry Complainant (for example, a member of the general public, healthcare professional, academic, Therapeutic Goods Administration) may lodge a complaint in relation to the activities of, or materials developed by, the Australian manufacturer/sponsor of a prescription product.

Complainants either as an individual/organisation or through the Independent Facilitator are encouraged to contact the Subject Company prior to lodging a complaint with Medicines Australia, as a satisfactory explanation or solution may be immediately available.

The preferred method of lodging of a non-industry complaint is by submitting the 'Complaints Submission Form for Non-industry Complainants', which is available on the Medicines Australia website: http://medicinesaustralia.com.au/code-of-conduct. The form can be lodged electronically, mailed or faxed to Medicines Australia.

Written complaints can be lodged via email, fax or letter.

To ensure a complaint receives the best consideration and that the responding company has full information, anonymous complaints will not be considered by the Code of Conduct Committee. If a non-industry Complainant wishes their name to remain confidential, the Medicines Australia Code Secretariat will not disclose the name of the Complainant to the Subject Company concerned, the Code of Conduct Committee, Appeals Committee or Monitoring Committee. Medicines Australia will not publish the name of a Non-industry Complainant in any reports on the outcomes of code complaints.

All documents relating to a complaint are required to be kept confidential until the complaint is deemed finalised.

Complaint

The complaint (whether via form, letter, fax or email) should where possible identify the following:

- Name of the company responsible for providing the information or undertaking the activity alleged to be in breach of the Code;
- Brand name of the medicine (if known);
- Approved name of the medicine (if known);
- Where the information appeared (for example a journal, magazine, newspaper or television);
- Date of publication/broadcast or activity;
- A copy of the material (where possible);
- Description of the matters believed to be in breach of the Code - identifying specific issues, claims or activities;
- Particular sections of the Code alleged to be in breach:
  - If a complaint is received by Medicines Australia, the Complainant will be offered the assistance of an Independent Facilitator to assist them to identify relevant sections of the Code.
  - If the offer of an Independent Facilitator is declined the Secretariat has the discretion to refer the complaint to the Monitoring Committee (permanent members) and request the Committee to advise whether all relevant Sections of the Code have been identified in the complaint. The Monitoring Committee will only identify additional Sections of the Code if there is an obvious omission by the Complainant.
  - This review will not alter or affect the general tenor or character of the complaint.
- Where the complaint is based on medical or scientific issues, evidence to support the complaint is desirable. Detailed literature reviews are not necessary, but where the complaint is based on scientific issues, supporting literature is desirable to ensure a balanced review. It is expected that where medical literature is cited, a copy of that literature will be made available to Medicines Australia by the Complainant for the purpose of review.
- Details of any attempts to resolve the matter;
- Name and contact details; and

- If the Complainant is not lodging the 'Complaints Submission Form for Non-industry Complainants' the following information should be provided:
    - Whether the Complainant does not wish to have their name and contact details provided to the pharmaceutical company;
    - Whether the Complainant wishes to use the services of an Independent Facilitator; and
    - A declaration of any conflict of interest.

Industry Generated Complaints

Intercompany Dialogue Guidelines

The purpose of the guidelines is to promote successful intercompany dialogue between companies and provide an official timeframe for companies to undertake dialogue. These guidelines apply to both members of Medicines Australia and non-Medicines Australia Member Companies. Dialogue between the Subject Company and the Complainant should be meaningful with a willingness from both companies to consider each other's position and concerns.

The following guidelines should apply to matters where it is clearly apparent that the lodgement of a Code of Conduct complaint is imminent. These guidelines are not designed to restrict dialogue between companies in order to clarify promotional issues.

- Medicines Australia will not accept a complaint from a company unless it has been clearly demonstrated that inter-company dialogue has taken place and that, despite every effort on the part of both the Complainant and the Subject Company, resolution of the matter has not been achievable.
- There must also be evidence of the active involvement of the Member Representative of the company responsible for the company's prescription products business in attempting to resolve the complaint. Section 4.4 (6) of the Medicines Australia Constitution states that this representative shall be the most senior executive officer of the Member whether described as Managing Director, Chief Executive Officer, General Manager, Regional Director or otherwise. For a non-member company this means the most senior executive responsible for the company's prescription medicines business.
- Medicines Australia will not accept a complaint from a company where there is no endorsement by the senior executive officer. If the senior executive officer is likely to be uncontactable when a complaint is lodged, a letter authorising the Medical Director to act as a signatory to the letter of complaint during a specified period will be acceptable.

Procedures

The Complainant and Subject Company are both encouraged to initiate dialogue at any point in the process.

- On receipt of a letter from the Complainant, the Subject Company must respond to any issues raised by the Complainant within ten (10) working days.
- From the receipt of the response to the issues raised by the Complainant, the Complainant and Subject Company must organise a meeting to discuss any unresolved issues within ten (10) working days. Such a meeting must occur before a complaint can be submitted to Medicines Australia.
- A teleconference or video conference may be an acceptable form of dialogue. An exchange of letters regarding the complaint will not usually be sufficient.
- Medicines Australia is willing to act as a mediator should the companies desire.
- If no agreed date has been finalised within ten (10) working days, direct contact between the senior executive officers of the two companies must occur and a meeting must be organised within two (2) working days.
- The Complainant and Subject Company have five (5) working days in which to finalise consensus minutes and agreed outcomes from the meeting. This record of the meeting must be submitted with the complaint should it proceed to Medicines Australia.
- If the senior executive officer of either company is not present at the intercompany dialogue, a record of the meeting must be provided to them. Evidence that the senior executive officer was informed of and acknowledged the record of the meeting must be submitted with the complaint or response to a complaint to Medicines Australia.
- If it is agreed that further intercompany dialogue is required this must be undertaken within a further ten (10) working days.
- If complaint is not resolved within this defined timeframe the complaint can be forwarded to Medicines Australia.

Resolution following intercompany dialogue

Following the process of inter-company dialogue, companies should have clearly documented the position of each party, for example including offers on the part of the Subject Company for resolution and whether or not the Complainant is willing to accept such offers. There should also be clear evidence of any corrective action undertaken by the Subject Company as a result of the inter-company dialogue.

If the Complainant proceeds to submit the complaint to Medicines Australia, the complaint should be accompanied by the consensus minutes of the intercompany meeting and any subsequent correspondence relating to offers for resolution and actions taken.

Should the complaint proceed for review by the Code of Conduct Committee, and there is evidence that corrective action has already been taken by the Subject Company, the Code of Conduct Committee may choose to take one or more of the following actions:

a) reduce the sanctions if the corrective action taken by the Subject Company is at least what the Code Committee would require; and/or
b) require the Complainant to justify their decision to progress the complaint to Medicines Australia in view of an apparent resolution at inter-company level; and/or
c) require the Complainant to justify why their action in submitting the complaint did not constitute a breach of Section 27 Abuse of the Code.

Complaint

Companies should ensure that they have included sufficient detail in their complaint to assist the members of the Code of Conduct Committee in making their decision:

The complaint must include the following information:

- Executive summary – summary of the complaint including sections of the Code alleged to be in breach;
- Detailed description of the complaint itemising specific claims in relation to each item of promotional material (please refer to items of promotional material by the alphanumeric identifier included at the end of the mandatory text, which specifically identifies the particular item or advertisement) and identifying the particular sections of the Code alleged to be in breach;
- State the nature of the practice being complained about with a clear explanation of the reasons to support the allegation of a breach of the Code;
- Where the complaint is based on medical or scientific issues, evidence to support the complaint must be provided. It is expected that where medical literature is cited, a copy of that literature will be made available to Code Committee by the Complainant for the purpose of review.
- Supporting data should be cross referenced to specific claims alleged to be in breach and a rationale for each allegation;
- Alleged consequences of the material or activity on healthcare professionals and/or consumers with supporting data or evidence, if available;
- Details of intercompany dialogue/attempts to resolve matter, including minutes of all meetings (whether in person or by teleconference); and
- All complaints must contain the written endorsement of the senior executive officer.

Withdrawal of complaints

Under the current provisions of the Code, the response from the Subject Company must be provided to Medicines Australia within ten (10) working days of receipt of the complaint notification. If companies are directed to, or wish to continue intercompany dialogue after the acceptance of a complaint and this action results in a decision by the Complainant to withdraw the complaint, notification must be provided to Medicines Australia by midday on the Monday prior to the next scheduled Code Committee meeting.

Limitation on complaints

Complaints will not be accepted by Medicines Australia where the promotional material or activity occurred in a period greater than 24 months from the lodgement of the complaint, unless the material or activity remained in force at the time of lodgement of the complaint. For example, if the advertisement was published in March 2007, a complaint lodged in August 2010 would not be accepted. However, if an item of printed promotional material was first published in September 2006 remained in circulation and in use at a trade display in February 2010; Medicines Australia would accept a complaint lodged in February 2010, if it also complied with other procedures such as intercompany dialogue.

Complaints process

- Complaint received by Medicines Australia (accepted as all procedures followed).
- Medicines Australia will forward the complaint to the Subject Company.
- Subject Company must provide a written response to Medicines Australia within ten (10) working days.
- Written complaint and response provided to the Code of Conduct Committee for a determination.
- *'Decision'* of the Code of Conduct Committee provided to the Complainant and Subject Company within two (2) working days.
- '*Decision and reasons for the decision'* provided to the Complainant and Subject Company within ten (10) working days.
- Notification of intent to appeal (Complainant or Subject Company) provided to Medicines Australia within five (5) working days of receiving the '*Decision and reasons for the decision'*.
- Written appeal submission provided to Medicines Australia within five (5) working days of the notification of intent to appeal.
- If no appeal lodged the complaint is deemed finalised.
- If appeal lodged Appeals Committee meeting convened as soon as practical.
- *'Decision'* of the Appeals Committee provided to the Complainant and Subject Company within two (2) working days.
- '*Decision and reasons for the Appeals Committee decision'* provided to the Complainant and Subject Company within ten (10) working days.
- On receipt of the '*decision and reasons for the decision'* the complaint is deemed finalised. No further action by the Complainant or Subject Company in relation to this complaint will be accepted by the Code of Conduct Committee.

All documents relating to a complaint are required to be kept confidential until the complaint is deemed finalised.

Repeat Breach

In the case of an alleged repeat breach of the Code, the Complainant may direct the complaint to Medicines Australia without a renewal of inter-company dialogue. However, Medicines Australia always encourages companies to continue to discuss any complaint prior to, and following a complaint being submitted to Medicines Australia.

Medicines Australia will not accept a complaint from a company in relation to an alleged repeat breach if the activity does not fall within the definition of 'repeat breach' or where new activities are introduced into the complaint. The complaint will be returned to the Complainant for the mandatory intercompany dialogue.

Inter-company complaints should not be used simply as a competitive tool.

Abuse of the Code

If a concern is raised that the complaint is frivolous or vexatious, before the Code Committee considers the matter it will request the Complainant Company to provide its response to the allegation, including any reasoning why the Committee should not impose a fine up to of a maximum of $200,000 for abuse of the Code of Conduct. The Complainant Company's response must be provided to Medicines Australia within ten (10) working days. The Complainant Company's response will be considered at the next Code Committee meeting.

Response by a Subject Company

When a complaint has been accepted by Medicines Australia, the Subject Company is asked to state whether or not the information supporting the complaint is correct, and to give any answer or explanation which may be deemed necessary.

Companies should ensure that they have included sufficient detail in their response to assist the members of the Code of Conduct Committee in making their decision.

When providing this information, the Subject Company should include:

- Executive summary;
- Response to each alleged breach raised by the Complainant;
- Where the complaint is based on medical or scientific issues, supporting evidence to rebut the complaint is desirable. If the supporting documentation (for example, an article from the published literature) has already been provided by the Complainant there is no requirement to submit another copy of the reference or study. If the Subject Company wishes to refer to a specific section of the study it should be identified by using the Complainant's appendix or reference number and specify the page and paragraph number.
- Supporting data should be cross-referenced to specific claims alleged to be in breach and rationale for defence;

- Details of intercompany dialogue/attempts to resolve issue(s). If the Subject Company is in agreement with the Complainant's recital of the intercompany dialogue this should be noted in the submission, and another copy is not required in response documentation. Where consensus minutes were not agreed upon the Subject Company should also enclose their record of the meeting.
- Evidence of early involvement of the senior executive officer in any complaint should be provided; and
- All responses must contain the written endorsement of the senior executive officer or in the case of a non-member company the Managing Director or head of the prescription medicines division.

The following is an extract of the Constitution of Medicines Australia (June 2014) which refers to membership issues and the disciplining of Members and rights of appeal.

4. Membership

4.4 Membership Issues

(4) Each Member shall conform to and be bound by the decisions addressed to them by the Code Committee, including but not limited to sanctions imposed by the Code of Conduct Committee.

. . .

(6) A Representative shall be the most senior executive officer of the Member whether described as Managing Director, Chief Executive Officer, General Manager, Regional Director or otherwise.

5. Disciplining of Members

5.1 Power

(1) Subject to the Act and this Constitution, the Board has the power by resolution to:

(a) suspend or expel a Member from the Company; or
(b) to censure or impose a fine on a Member.

(2) Without limiting it power under part (1) of this clause, the Board may exercise its power under this clause if the Member:

a. wilfully refuses or neglects to comply with the provisions of this Constitution;
b. is guilty of any conduct which in the reasonable opinion of the Board is:
   i contrary to the Objects;
   ii contrary to the Code of Conduct;
   iii in breach of a sanction imposed by the Code of Conduct Committee;
   iv prejudicial to the interests, image or welfare of the Company; or
   v likely to bring discredit upon the industry; or
c. fails to pay to the Company any moneys due by the Member to the Company after notice has been given.

(3) For clarity, power of the Board under clauses 5.1(1) and 5.1(2) is separate to the authority vested in the Code of Conduct Committee and resolutions made by the Board under clauses 5.1(1) and 5.1(2) are independent of and in addition to any sanctions (if any) imposed by the Code of Conduct Committee, notwithstanding that the Board may rely on evidence, submissions and conclusions of the Code of Conduct Committee.

5.2 Disciplinary Meeting

(1) The Board must exercise its power under clause 5.1 at a meeting to be held not earlier than 14 days and not later than 28 days after service on the Member of a notice:

(a) setting out the resolution by which the Board proposes exercising its power under this clause and the grounds on which the Board relies;
(b) stating that the Member may address the Board at the meeting;
(c) stating the date, place and time of that proposed meeting; and
(d) informing the Member that the Member may do either or both of the following:
   i. attend and speak at the meeting; and
   ii. submit to the Board not less than one day prior to the date of that meeting written representations relating to the resolution proposed.

(2) At a meeting of the Board held pursuant to clause 5.2 (1), the Board:

(a) shall give to the Member an opportunity to make oral representations;
(b) shall give due consideration to any written representations submitted to the Board by the Member prior to the meeting;
(c) may hear from any other person on the matters alleged in the grounds notified to the Member;

(d) may by resolution determine whether to pass or reject the resolution notified or as amended, as the case may be;
(e) may amend the resolution notified to the Member, but not so as to impose a more severe penalty than that stated in the notice to the Member nor a fine greater than a fine stated in the notice to the Member; and
(f) may proceed to consider the matter in the absence of the Member.

(3) In the course of its deliberations when exercising its powers under clause 5.1, the Board may:

(a) act on the recommendation, information or advice of any committee of the Company;
(b) may act through (whether in whole or in part) any committee permitted by the Board to consider matters before it;
(c) consider such evidence as it considers reasonably appropriate;
(d) make its own inquiry (but without being bound to do so); and
(e) make its decision according to the matters before it, determining the weight and relevancies according to its own considerations without further review being available except as this Constitution expressly permits.

(4) Where the Board passes a resolution at a meeting held pursuant to clause 5.2 (1), the Secretary shall inform the Member in writing of the fact and of the Members rights of appeal under clause 5.3.

(5) A resolution passed at a meeting held pursuant to clause 5.2 (1) does not take effect:

(a) until the expiration of the Appeal Period; or
(b) if within the Appeal Period the Member exercises its right of appeal, unless and until the Company confirms the resolution pursuant to clause 5.3.

5.3 Right of Appeal of Disciplined Member

(1) A Member may appeal to the Company in a general meeting against a resolution of the Board passed under clause 5.2, by lodging with the Secretary within the Appeal Period:

(a) an Appeal Notice; and
(b) an upfront fee of $5,000 or such other amount as may be determined by the Board from time to time, to defray costs associated with the cost of convening the general meeting.

(2) Upon receipt of an Appeal Notice and payment within the Appeal Period, the Secretary shall notify the Board and shall convene a general meeting of the Company to be held not less than 21 days but not more than 45 days after the date on which the Secretary received the Appeal Notice and payment.

(3) The fee paid by the Member under this clause 5.3:

(a) will be refunded to the Member if the appeal is upheld; and
(b) will not be refunded if the resolution is upheld unless the fee paid exceeds the costs of holding and minuting the meeting, including such reasonable allowances for the Company in preparing for and advising on the meeting and its procedure, including any associated legal costs, whereupon that excess shall be refunded.

(4) At a general meeting of the Company convened under clause 5.3:

(a) no business other than the question of the appeal shall be transacted;
(b) the Board and the Member shall be given the opportunity to state its respective cases orally or in writing, or both; and
(c) the Members present shall vote by secret ballot on the question of whether the resolution should be confirmed or revoked.

(5) If at the general meeting the Company passes a resolution in favour of the confirmation of the resolution, the resolution is confirmed. If the resolution fails then the resolution of the Board under clause 5.2 is revoked.

. . .

15.2 Amendments to the Code of Conduct

(1) The Company must establish and maintain a Code of Conduct.

(2) The Code of Conduct must provide for a Code of Conduct Committee to administer Code of Conduct, noting that such administration includes:

a) Reporting to the Board on the scope, drafting and adequacy of the Code of Conduct;
b) The capacity to investigate breaches of the Code of Conduct;
c) Addressing complaints arising under the Code of Conduct; and
d) The capacity to lay complaints for a breach of the Code of Conduct.

(3) The Company hereby confers on the Code of Conduct Committee all the power and authority to:

a) administer the Code of Conduct complaints procedures, including the conduct of investigations;
b) decide whether the Code of Conduct has been breached or abused;
c) carry out the procedures contained within the Code of Conduct; and
d) impose sanctions on Members who are found by the Code of Conduct Committee (including by any appeals committee) to have breached the Code of Conduct, which sanctions may include but shall not be limited to:
    i monetary fines;
    ii directions concerning actions which in the view of the Code of Conduct Committee infringe or which risk infringing the Code of Conduct
    iii directions rectifying, remedying or mitigating the effect or consequence of actions which in the view of the Code of Conduct Committee infringe or which risk infringing the Code of Conduct;

(4) The Code of Conduct must provide for a process for appeal for Members (and others) who are found by the Code of Conduct Committee to have breached the Code of Conduct and:

a) any appellate committee formed for that purpose under the Code of Conduct shall have all the power and authority of the Code of Conduct Committee under clause 15.2(c);
b) Each reference in this Constitution to the "Code of Conduct Committee" other than the references in clauses 15.2(b), 15.2(c) and this clause 15.2(d) is deemed to include a reference to each and any appellate committee formed for the purpose of this clause 15.2(d); and
    a. the reference in clause 4.4(4) to a "decision addressed to a Member by the Code of Conduct Committee" shall be a reference to each decision of an appellate committee formed for the purpose of this clause 15.2(d) which has reviewed any such decision by the Code of Conduct Committee; and
    b. the references in clauses 4.4(4), 5.1(2)(b)(iii) and 5.1(3) to a "sanction imposed by the Code of Conduct Committee" shall be a reference to each sanction (including a decision to overturn a sanction) of an appellate committee formed for the purpose of this clause 15.2(d) which has reviewed any such sanction imposed by the Code of Conduct Committee;

(5) For clarity, the power and authority conferred under clauses 15.2(c) and 15.2(d) is authority that is in addition to and independent of authority conferred by the Board and:

a) the Board may vest in the Code of Conduct Committee such additional authority as it sees fit; and
b) the Code of Conduct may impose on the Board responsibilities of oversight of the conduct of the committees established under the Code of Conduct.

(6) The Code of Conduct must only be amended if the formal process in this clause 15.2 is followed. However, nothing in this clause 15.2 prohibits the Board from informally seeking Member consultation on any proposed amendments to the Code of Conduct.

(7) A proposal to amend the Code of Conduct must be submitted for approval by the Members which approval must be given by the passing of special resolution.

(8) If a proposal to amend the Code of Conduct is approved by the Members in accordance with clause 15.2(7) and the amended Code of Conduct receives any regulatory authorisation the Board considers appropriate, the Board must:

a) do all things necessary to give effect to the amended Code of Conduct; and
b) notify all Members and any other parties who voluntarily comply with the Code of Conduct of the amendments.

APPENDIX 3 • SUMMARY OF EVENTS SPONSORED BY MEMBER COMPANIES

Reporting Period (For example, October 2014 - March 2015)

Company Name:

Number of events held:

Description of function including duration of educational content delivered	**Venue**	**Professional status of attendees**	**Hospitality or financial support provided**	**Total cost of hospitality**	**No. of attendees**	**Total cost of function**
Companies to provide as much information as they feel necessary to explain the educational component For example: • Type of function • Nature of education provided • Program accreditation e.g. CPD points • Length of educational component	Specify: • Venue name • Location	Specify: For example: • Anaesthetists • General Practitioners	Specify: The nature of the hospitality provided and whether it included any of the following elements: • Food and/or beverages • Accommodation • Travel expenses • Sponsorship to attend • Event registration fees • Entertainment	$ cost This must state the total cost of the items listed in the hospitality column. A breakdown of those costs may be provided if desired.	XX	$ cost Including: • Total speaker fees, chairperson fees, or faculty remuneration • Venue hire • Transportation costs • Materials provided to attendees etc. • Hospitality costs • Third party costs such as event organiser • Audio visual costs

APPENDIX 4 • SUMMARY OF ADVISORY BOARDS CONVENED BY MEMBER COMPANIES

Reporting Period (For example, October 2014 - March 2015)

Company Name:

Number of meetings held:

	Venue	**Professional status of Members**	**Total Honoraria and/or sitting fees provided**	**Total Hospitality provided and cost**	**Total No. of participants**	**Total cost of event**
• Company identifier for Advisory Board	Specify: • Venue name • Location	Specify: For example: • Clinicians • Nurses • Pharmacists • Consumer • Other	• Total cost	Total $ cost The nature of the hospitality provided and whether it included any of the following elements: • Airfares, • Accommodation • Food and/or beverages • Travel expenses.	XX (excluding company staff)	Total $ cost Including: • hospitality costs • honoraria and/or sitting fees • third party costs • audio visual • venue hire

APPENDIX 5 • SUMMARY OF HEALTH PROFESSIONAL CONSULTANCIES ENGAGED BY MEMBER COMPANIES

Reporting Period (For example, 1 January 2014 – 31 December 2014)

Company Name:

	Total consulting fee provided	**Total Hospitality provided and cost**	**Total No. of consultants**	**Total cost of consulting services**
• Total consultancies per annum	Total $ cost	Total $ cost The nature of the hospitality provided and whether it included any of the following elements: • Accommodation • Food and/or beverages • Travel expenses.	XX (excluding company staff)	Total $ cost Including: • consulting fees • hospitality costs

APPENDIX 6 • SUMMARY OF HEALTH CONSUMER ORGANISATION SUPPORT BY MEMBER COMPANIES

Reporting Period (For example, 1 January 2014 – 31 December 2014)

Company Name:

Name of Health Consumer Organisation	**Description of and/or purpose of the support**	**Nature of support – monetary value (or equivalent) or description of non-financial support**
	A description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the nature of the support	The monetary value of financial support and of invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value, the published information must describe clearly the non-monetary value that the organisation receives

GLOSSARY

In this Code:

Adverse effect has the same meaning as **Adverse Drug Reaction**, which is a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for modification of physiological function. Adverse effects are listed in the Product Information.

Advertisement in relation to therapeutic goods as defined in the Therapeutic Goods Act 1989 includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.

Advisory Board means a group of healthcare professionals with specific expertise contracted by a company to meet at regular intervals to provide advice on a Company's Product or group of products.

Association means Medicines Australia Ltd.

Australian Approved Names means the active ingredients or chemical components of a product.

Australasian Congress means a congress held in Australia that is organised and controlled by an Australasian (or Australian and New Zealand) College or Society, or where a College or Society in New Zealand is actively organising and has joint control over the congress with an Australian Society or College.

Australian Privacy Legislation means the Privacy Act 1988 (Cth) and related legislation.

Boxed Warning is a mechanism adopted by the TGA for highlighting special warning statements in Product Information.

Brand name for the purpose of the Code of Conduct has the same meaning as 'proprietary name' which is the registered trade mark of the therapeutic product or the unique name assigned to the product.

Brand name reminders means such items of low monetary value which are intended to remind healthcare professionals of the existence of a product.

Breaches where activities have ceased means Severe Breaches of this Code where the promotional activity has been completed before the breach has been found and there is no opportunity for corrective action.

Change of clinical significance is any change in the Product Information that is likely to alter a decision to prescribe or not to prescribe the product and may include the following:

a) approved indications for use
b) precautions for use
c) contra-indications
d) warnings
e) adverse effects and interactions
f) available dosage forms
g) dosage regimens and routes of administration
h) dependence potential
i) reference to special groups of patients (where necessary)
j) boxed warnings

Chief Executive means that person appointed to manage the affairs of Medicines Australia (also known as the Association) in accordance with the Constitution of Medicines Australia.

Clinical research means planned research involving humans which is designed to investigate and report upon the effectiveness (including, but not limited to pharmacokinetics, dosage regimens, routes of administration, efficacy) and/or safety (including tolerability, immunogenicity, side effect profile, drug interactions) of a medicine. (see also Phase I, II and III clinical trials)

CMI means Consumer Medicine Information.

Code Guidelines means the current Code of Conduct Guidelines.

Code of Conduct Secretary means that person appointed by the Medicines Australia Board to act as Secretary to the Code of Conduct Committee.

Company means all companies supplying prescription products in Australia.

Company Commissioned article (also known as an advertorial) means an article or series of articles which is paid for by a Company which represents the independent opinion of a third party and/or has the appearance of editorial material.

Company representatives are those persons, including medical representatives, authorised by a Company to disseminate information about a product to healthcare professionals.

Competition means any activity that includes an element of chance or random selection.

Congress means an event sponsored and organised by a Society, College, university or other non-company entity.

Constitution means the Constitution of Medicines Australia Ltd for the time being in force (See Appendix 2).

Consultant means an Australian healthcare professional or a group of Australian healthcare professionals providing consulting services to a company in relation to specific projects. For the purpose of reporting consultant services, these are regarded as different from providing advice as a member of an Advisory Board.

Consumers are persons other than healthcare professionals.

Consumer Medicine Information (CMI) is information about products written by the pharmaceutical company that makes the product. It is easy to understand and written for consumers. Companies writing CMI leaflets follow guidelines to ensure the information is accurate, unbiased, and easy to understand. A separate CMI leaflet is available for each prescription and many non-prescription products.

Correct means representative of all the evaluable data.

Data on File is that body of unpublished clinical or scientific information held by a company. It does not include evaluated data submitted to the TGA in accordance with the *Australian Regulatory Guidelines for Prescription Medicines.*

Educational material means any representation or literature which is intended to provide information about a medical condition or therapy which does not contain specific promotional claims.

Entertainment means the provisions of any diversion or amusement.

Evaluated data means data which have been submitted as part of an application for marketing in accordance with the *Australian Regulatory Guidelines for Prescription Medicines* which form the basis for registration of a product by the TGA.

General Public are persons other than healthcare professionals.

Graphics means the use of any pictorial or graphical representation in promotional material, including photographs, drawings, x-rays, graphs and bar charts, but excludes any related promotional text.

Healthcare professional means a healthcare professional registered to practice in Australia who in the course of their professional activities may prescribe, dispense, recommend, supply or administer a prescription medicine in Australia.

Health consumer organisations are not-for-profit organisations that represent the interests and views of consumers of health care. They may range from small volunteer groups to large organisations, and generally promote views that are independent of government, the pharmaceutical industry and professional health service providers.

Hospitality means the provision of food and/or beverages.

IFPMA means International Federation of Pharmaceutical Manufacturers and Associations.

Information means educational facts regarding the attributes of a product.

Industry means companies supplying prescription products in Australia.

International congress means a congress held in Australia where a Society or College in an overseas country is actively organising and has joint control over the conference with an Australian Society or College.

Journal means a serial publication whose distribution is restricted to the members of the healthcare professions.

Literature means that body of published trials, findings and reviews which have appeared in medical and scientific publications.

Mailings means promotional material designed for distribution through the postal system or by private means.

Market research is the gathering of data on the scope or dimensions of a market and its components, including the needs of the customers in that market.

Medical claims includes any statement that conveys information about a disease state or the attributes of a product in respect of its **therapeutic use**, that is, a use in or in connection with:

a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons;
b) influencing, inhibiting or modifying a physiological process in persons;
c) testing the susceptibility of persons to a disease or ailment; or
d) controlling or preventing conception in persons; or
e) testing for pregnancy in persons; or
f) the replacement or modification of parts of the anatomy in persons.

Medical Information websites contains information and standard responses prepared by the Medical Information function in order to provide education or resources for Australian healthcare professionals. The website must not contain any advertising or promotional information.

Medical representative means a person expressly employed by a company whose main purpose is the promoting of the company's products to healthcare professionals.

Medicine delivery device is any device used for the administration of a prescribed product, including Schedule 3 products that are predominantly prescribed by a medical practitioner that is distributed independently from the active ingredient. The device will be listed with the TGA as a device.

Medicines Australia endorsed education program means the professional training program developed by Medicines Australia and which is compulsory for all medical representatives employed by pharmaceutical companies. Also known as the Continuing Education Program (CEP).

Member means an entity registered as a Member of Medicines Australia Ltd.

Member Representative means the most senior executive officer of the Member whether described as Managing Director, Chief executive Officer, General Manager or otherwise as set out in Section 4.4 (6) of the Medicines Australia Constitution (See Appendix 2). For a non-member company the equivalent company representative is the most senior executive officer responsible for the company's prescription medicines business.

Minor breach is a breach of this Code that has no safety implications to the patient's wellbeing and will have no major effect on how the medical profession will prescribe the product.

Moderate breach is a breach of this Code that has no safety implications to the patient's wellbeing but may have an effect on how the medical professional will prescribe the product.

New chemical entity means a product containing an active pharmaceutical ingredient which has not been previously included in a product approved for registration in Australia for human use, including new combinations, salts or esters of previously marketed substances. For the purposes of the Code of Conduct this term includes biological active ingredients.

New indication(s) means an additional indication for the drug which is approved by the TGA after the original registration of the drug.

Patient Support Program means a program run by a company with or without involvement from a health consumer organisation, with the aim of increasing patient compliance and positive patient health outcomes.

Pay journal means a journal that accepts a fee for publication.

Personal information has the same meaning as the *Privacy Act 1988* (*Cth*)

PBS means the Pharmaceutical Benefits Scheme of the Commonwealth Department of Health.

PBS availability means the availability of a product on the Pharmaceutical Benefits Scheme of the Commonwealth Government.

Phase I Clinical Trial means studies which involve the first administration of the medicine to humans. Medicines are usually given to small numbers of healthy volunteers, but sometimes to people affected by the disease the medicine is intended to treat. The purpose may be to determine the medicine's safety, pharmacokinetics, pharmacological activity, side effects, preferred routes of administration, or appropriate doses (for later studies). The studies are usually undertaken in centres equipped for specialised monitoring and a high degree of surveillance.

Phase II Clinical Trial means studies that are typically the first trials of the medicine in people with the health condition for which the medicine is intended. The principal aim is to determine efficacy and safety and establish an appropriate dosing regimen. These studies are undertaken in a small number of closely supervised patients and conducted by researchers regarded as specialists in the health condition and its treatment.

Phase III Clinical Trial means studies that are undertaken if the Phase II studies indicate the medicine has potential benefits that outweigh any hazards. The studies involve greater numbers of patients with the health condition under study, and aim to determine whether the medicine confers clinical benefit in that health condition and whether the

incidence and nature of adverse effects are acceptable. Phase IV trials allow for the gathering of even more detailed information about the treatment after it has become available to the public, such as economic and long-term safety information.

Post-marketing surveillance studies means research intended to generate data on safety parameters of a product that has been approved for registration when used in accordance with the approved Product Information.

Prescribing software means a programs on the healthcare professional's computer which are used in the decision making process with a patient prior to generating a script. They may also contain patient records, Product Information, access to information on drug interactions and other educational information.

Primary advertisement is the type of advertisement that is mandatory for advertising of all new chemical entities or the advertising of new indications for 24 months from the date of first advertising in medical publications, or longer at the discretion of the company. Primary advertisements must also be used for at least 12 months following a change of clinical significance made to a product's Product Information. These advertisements are described in Section 2.1.1.1 of this Code.

Product means any pharmaceutical dose form and/or delivery method that is approved for registration by the TGA for human therapeutic use, provided that such compound has been scheduled for sale or distribution by prescription only in at least one of the States of Australia or that such compound is primarily promoted to medical practitioners for the purpose of encouraging them to prescribe or recommend usage of that compound.

Product Familiarisation Program means a program run by the company with the aim of allowing the medical profession to evaluate and become familiar with the product following TGA registration and/or approval of new indications.

Product Information means either the current Australian Approved Product Information or in the case of a product whose registration pre-dates the current regulatory review ('Grandfathered Product') the document registered is known as the 'Full Product Information'. This Product Information must comply with the format specified in the TGA *Australian Regulatory Guidelines for Prescription Medicines.* Product Information may also be presented as a Minimum Product Information.

Product Manager means any person who is directly involved in the generation and development of promotional material. The identification of these individuals is the responsibility of the Association Representative.

Promote means, in the context of the definition of 'advertisement', all informational and persuasive activities, the purpose, actual or likely effect of which is to induce or discourage the purchase, sale, supply and/or use of therapeutic products.

Promotion, Promotional or Promotional claim means any statement made by a company or company's representative, whether verbal or written, which conveys the positive attributes of a product which extend beyond a simple non-qualitative or quantitative description of the therapeutic category or approved indication for the purpose of encouraging the usage of that product. It includes statements concerning efficacy, rate of adverse effects or other cautionary aspects of the product and comparative information.

Promotional material means any representation concerning the attributes of a product conveyed by any means whatever for the purpose of encouraging the usage of a product.

Proprietary name means the registered trade mark of the therapeutic product or the unique name assigned to the product. For the purpose of the Code of Conduct, brand name has the same meaning as proprietary name.

Quality Use of Medicines (QUM) means:
- selecting management options wisely
- choosing suitable medicines if a medicine is considered necessary
- using medicines safely and effectively

Reference manual is a serial or monographic publication designed by its publisher to provide information in classified sequence for the purposes of ready reference to pharmacological or medical data.

Registration is the issue by the TGA of an AUST.R number for a product approved for marketing in Australia in accordance with the Therapeutic Goods Act and Regulations.

Repatriation Pharmaceutical Benefit availability means the availability of a product on the Repatriation Pharmaceutical Benefit Scheme of the Commonwealth Government.

Repeat of previous breach means where the same or similar breach is repeated in the promotion of a particular product of a company which had been found in breach.

Research and development includes any early-stage research, such as target discovery, drug discovery, mechanism of action or proof of concept studies; pre-clinical research, such as toxicological studies; and human clinical trials.

Satellite Meetings are meetings held in conjunction with international or Australasian congresses and are under the auspices of the Society, College or other non-company entity in question.

Secondary advertisement is the type of advertisement that is designed to reinforce information about a product, and may contain promotional claims. The sole use of a Secondary advertisement within a single issue of a publication is not permitted before 24 months from first advertising of a new chemical entity or before 12 months following a change of clinical significance made to the Product Information. These advertisements are described in Section 2.1.1.2 of this Code.

Senior executive officer means the most senior executive officer of the Member whether described as Managing Director, Chief Executive Officer, General Manager, Regional Director or otherwise as set out in Section 4.4 (6) of the Medicines Australia Constitution (See Appendix 2). For a non-member company this means the most senior executive responsible for the company's prescription medicines business.

Serious in the context of advertisements for therapeutic products means those diseases, conditions, ailments and defects (or symptoms of the aforementioned) which are generally accepted as not being suitable.

Severe breach is a breach of this Code that will have safety implications to the patient's wellbeing, and/or will have a major effect on how the medical profession will prescribe the product and/or will have a significant commercial impact on the relevant market. A Severe breach of the Code will also be found for activities that bring discredit upon or reduce confidence in the pharmaceutical industry.

Short advertisement is the type of advertisement that is designed to remind a prescriber of a products existence but must not contain promotional claims. The sole use of a Short advertisement within a single issue of a publication is not permitted before 24 months from first advertising of a new chemical entity or before 12 months following a change of clinical significance made to the Product Information. These advertisements are described in Section 2.1.1.3 of this Code.

Social Media is an umbrella term that incorporates the various online platforms and activities that engage users to participate in, comment on and create digital content on the internet to allow them to interact, share information and network with others, including peer-to-peer conversations. Examples of social media include Facebook, YouTube, Myspace, Twitter, blogs and wikis.

Sponsor is defined in the current Therapeutic Goods Act.

Starter pack means a small pack size of a product supplied at no cost to medical practitioners, dentists and hospital pharmacists. Starter packs are also referred to as 'samples' by healthcare professionals.

Substantiation means to give reasonable grounds in support of a promotional claim. Substantiating information should conform with the requirements of Section 1.2, and must not rely solely on data on file.

Supplier means the same as 'company' – companies supplying prescription product in Australia.

Symposium means a scientific meeting sponsored by a Company as an independent event or as a satellite to a congress.

Tagline means a phrase or statement consistently associated with a brand name.

Technical breach means a breach of this Code that refers to the type size that is specified in this Code or inaccurate or incorrect referencing.

Therapeutic class means the classification system used for defining and grouping products in an approved reference manual.

Therapeutic class number means the system of notation used in an approved reference manual.

Therapeutic Goods Administration (TGA) is the Division of the Commonwealth Department of Health that is responsible for the regulation of therapeutic goods in Australia.

Trade Display means a display or exhibit of promotional or educational material about a product or products.

Trade pack means a package of a product which is sold by the Company.

Transfer of Value means a direct or indirect transfer of value, whether in cash, in kind or otherwise. A direct transfer of value is one made directly by a company for the benefit of the recipient. An indirect transfer of value is one made by a third party on behalf of a company for the benefit of a recipient where the identity of the company is known to, or can be identified by, the recipient.

Type size means the height of the font's lower case letter 'e'.

Unique means being the first, different from all others and the only one of its class on the Australian market.

NOTES

NOTES

NOTES

NOTES

NOTES

NOTES