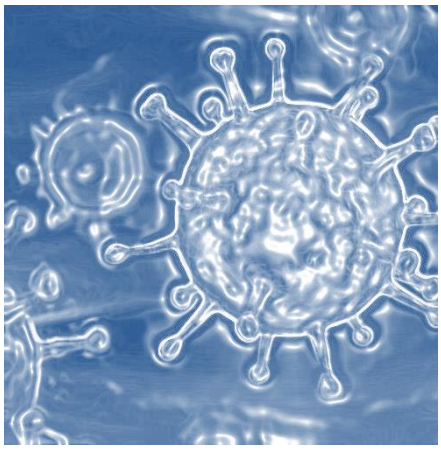
MEDICINES Australia



Code of Conduct Guidelines

Version 2 (October 2016)

To be read in conjunction with Code of Conduct Edition 18

DISCLAIMER

The Edition 18 Guidelines (Version 2) is provided for guidance only and does not cover all Code provisions. Pharmaceutical companies should not rely on this document alone. Please refer to Edition 18 of the Code of Conduct for all provisions.

FURTHER INFORMATION

Please contact Medicines Australia

Phone: 02 6122 8500

Fax: 02 6122 8555

Email: CodeHelpDesk@medicinesaustralia.com.au

Website: www.medicinesaustralia.com.au

Postal: Level 1
16 Napier Close
Deakin ACT 2600

ABN: 23 126 990 001

VERSION 2

Version 2 of the Guidelines is effective from October 2016.

CODE OF CONDUCT GUIDELINES • EDITION 18

CONTENTS

Introduction **6**

Section 1 Nature and Availability of Information and Claims **7**

Section 1.1 Responsibility 7

Section 1.2 Substantiating Data 7

Section 1.3 False and Misleading Claims 9

Section 1.4 Unapproved products and Indications 20

Section 1.8 Comparative Statements 23

PBS Disclosure Requirements **24**

Background 24

Section 2.1 Print Media 24

PBS and Product Information for items containing small advertisements 28

Section 2.2 (Electronic and Audiovisual media including Electronic Detail Aids), Section 2.3 (Restricted Access Television) and Section 2.4 (Internet, social media and eNewsletters) and materials designed for mobile media platforms 34

Section 2 Promotional Material directed at Healthcare Professionals **36**

Section 2.1 Print Media 36

Section 2.1.2 Printed Promotional material directed at healthcare professionals 37

Section 2.1.3 Mailing of printed promotional material to healthcare professionals 37

Section 2.2 Electronic and Audiovisual Media including electronic Detail Aids (e-Detail Aids) 38

Section 2.3 Restricted Access Television 39

Section 2.4 Internet, social media and e-Newsletters 40

Section 2.4.1 Company controlled websites for Healthcare Professionals 40

Webinars 40

Section 2.4.2 Social Media 41

Section 2.5 Prescribing Software 47

Section 2.6 Brand Name Reminders and items for medical education 48

Section 2.7 Competitions 49

Section 2.8 Communication with healthcare professional media 50

Section 2.8.3 Sponsorship of Medical Journalists to attend medical conferences 50

Section 3 Types of Product Information for inclusion with promotional material directed at healthcare professionals **51**

Section 3.2 Minimum Product Information 51

Section 3.3 Changes of Clinical significance and the addition of a Boxed Warning 51

Section 4 Educational Material directed at Healthcare Professionals **52**

Section 4.1 Medical Education and Section 4.2 Medical Literature/Reprints 52

Section 5 Company Representatives – Roles and Ethical Conduct **54**

Section 5.3 State Departments of Health, Hospital policies and operating theatre procedures 54

Section 5.5 Appointments with healthcare professionals 55

Section 5.9 Access to healthcare professionals 55

Section 6 Company Representatives – Education **56**
The Continuing Education Program 56
Section 6.5 Requirement to complete Program 1 Code of Conduct of the Continuing Education Program 57
Section 6.6 Australian Privacy & Competition and Consumer Legislation 57
Section 7 Starter Packs **58**
Section 8 Product Familiarisation Programs (PFPs) **61**
Section 9 Relationship with healthcare professionals **62**
Section 9.1 General Principles 62
Sections 9.3 Educational Events, 9.4 Company Educational Events held in Australia and 9.5 Sponsored Educational Events 63
Section 9.4.1 Educational content at Company Educational Events 63
Section 9.5 Sponsored (third party) Educational Events 64
Section 9.4.2 Venue selection (Company organised Educational Events) and 9.5.4 (Sponsored Third Party Educational Events) 66
Sections 9.4.3 & 9.5.5 Meals and Beverages/Hospitality 66
Section 9.4.4 Travel (company organised educational events held in Australia) 67
Section 9.4.5 Accommodation (Company organised meetings in Australia) 68
Sections 9.4.6 and 9.5.8 Entertainment 68
Sections 9.4.8 and 9.5.7 Costs incurred by partners, travelling companions or families of healthcare professionals 68
Sections 9.4.9 and 9.5.9 Provision of company-branded items at educational events 69
Invitations to Company Educational Meetings 72
Section 9.6 Trade Displays 76
Section 9.7 Sponsorship of healthcare professionals to attend educational events 77
Section 9.7.5 Sponsoring travel to attend Australasian and international educational events 77
Section 9.7.7 Meals and beverages provided to healthcare professionals attending international educational events 78
Section 9.8 Consulting Arrangements and Section 9.9 Advisory Boards 78
Section 9.10 Company supported medical practice activities 78
Section 9.11 Grants and Financial Support 81
Section 9.12 Gifts and Offers 82
Section 9.13 Discredit to and reduction of confidence in the industry 82
Research **83**
Clinical research 83
Section 11 Ghost writing 83
Section 12 Market Research 83
Section 13 Relationship with the General Public **85**
Section 13.1 General Principles 85
Section 13.4 Product Specific Media Releases 85
Section 13.5 General Media Articles 86
Section 13.6 Educational information available to the general public 87
Section 13.7 Materials for use with patients (Patient Aids) 87
Section 13.9 Use of the Internet 88
Section 13.10 Social Media 89
Section 14 Relationships with Health Consumer Organisations **91**
Sponsorship of Health Consumer Organisations and educational grants 91

Section 17 Patient Support Programs **95**
Disclosure of payments to healthcare professionals 95
Section 19 Discredit to and Reduction of Confidence in the Industry **95**
Transparency Reporting Requirements **96**
A. Reporting Transfers of Value to healthcare professionals from 1 October 2015 97
B. Reporting Requirements ongoing from Code Edition 17 and for the duration of Code Edition 18 102
C. Reporting Sponsorship of Third Party Educational meetings and Symposia from 1 October 2015 103
Sponsorship of Third Party Educational Meetings Report Timelines 103
Code Administration **125**
Section 27 Abuse of the Code 127
Section 28 Sanctions 127
Section 31.2 Monitoring Procedures 131
Monitoring Committee Submission Guide 131
Medicines Australia Code of Conduct Committee submission format 134
Acknowledgements **138**
Working Group Members 138
Medicines Australia Secretariat 138

LIST OF TABLES

1 PBS and Product Information for items containing small advertisements 29
2 PBS and Product Information in advertisements in audiovisual, restricted access television, internet and eNewsletters 34
3 Provision of company and product branded items 69
4 Example Reporting Table for Support for Health Consumer Organisations (HCOs) 93
5 Summary of Reporting requirements 96
6 Guidance recommending appropriate conduct for educational events 104
7 Reporting Table for Sponsorship of Third Party Meetings and Symposia 111
8 Example of a Completed Third Party Meetings and Symposia Sponsorship Report 112
9 Reporting Template for Payments and Transfers of Value to Healthcare Professionals 114
10 Reporting of Payments and Transfers of Value to Healthcare Professionals – Frequently Asked Questions 115
11 Summary of materials and activities reviewed by the Monitoring Committee 2011-2016 144

LIST OF FIGURES

1 When is a qualifying statement required? 12
2 Example of a primary advertisement with a referenced claim and qualified tagline 14
3 Example of a primary advertisement with a claim and qualifying statements 15
4A Example of a primary advertisement with a multi-level claim and qualifying statement 16
4B Example of a primary advertisement with a multi-level claim and qualifying statement in the wrong location 17
5A Extract from a multi-page detail aid – study details, location “Not significant” 18
5B Extract from a multi-page detail aid – study details, location “NS” 19
6 Medical telephone message advertisement – no qualifying statement 31

7 Medical telephone message advertisement – with qualifying statement 31
8 Doctors desk set advertisement 32
9 Diary advertisement – no qualifying statement 32
10 Diary advertisement – with qualifying statement 33
11 Short advertisement for Calendar 33
12 eNewsletter advertisement 43
13A Opening screen for e-Detail aid - smart phone 44
13B Advertising screen with promotional claim and reference - smart phone 44
13C Location of Product Information and PBS Information in e-Detail aid - smart phone 45
13D Location of Product Information and PBS Information in e-Detail aid - smart phone 45
14A Opening screen for e-Detail aid - tablet device 46
14B Location of Product Information and PBS Information in e-Detail aid - tablet device 46
14C Location of Product Information and PBS Information in e-Detail aid - tablet device 47
15 Company branded item of medical education 49
16 Sponsorship of third party educational events 65
17 Company branded notepad 70
18 Company and corporate division branded notepad 70
19 Non-compliant company branded notepad 71
20 Company branded pens 71
21A Invitation to a company educational event 74
21B Invitation to a company educational event 75
22 Example of a 'Medical Practice Activity Agreement' 80
23 Propose Collection Statement 99
24 Proposed Verification Letter Template 101
25 Proposed Reporting Website Wording 102
26 Reporting Payments to Healthcare Professionals under Reasonable Expectations from 1 October 2016 110
27 Complaints and appeals process summary 126
28 Corrective letter format 129
29 Monitoring Committee process summary 136

Introduction

These Guidelines have been written to assist companies in complying with the provisions of the Medicines Australia Code of Conduct (the Code). The Guidelines provide insight both into the experiences of the Code of Conduct, Appeals and Monitoring Committees and the deliberations of Medicines Australia and its members when developing amendments to the Code of Conduct.

These Guidelines are a living document and will be augmented as issues are raised by members or other interested people.

The Guidelines must be read in conjunction with the Code of Conduct. When considering whether a particular item of promotional or educational material or any other conduct complies with the Code, companies should first read the relevant Code provisions and then consider any additional guidance provided in these Guidelines.

A company must consider what is 'reasonable', within the spirit of the Code, and whether the proposed conduct is consistent with ethical conduct of the industry and that company.

These Guidelines do not cover all sections of the Code. For convenience, some sections of the Code have been grouped together, such as those provisions dealing with PBS information disclosure.

If you would like any further assistance regarding specific provisions of the Code, what the Code is trying to achieve or its administration, please contact Medicines Australia via the Code Help Desk email: Codehelpdesk@medicinesaustralia.com.au.

Section 1 Nature and Availability of Information and Claims

Section 1.1 Responsibility

A Company's responsibility is to provide a fair and balanced representation of both the safety and efficacy of a product or comparison between products. Companies should ensure that adequate safety information is included in relation to efficacy or other promotional claims.

There is no definitive position on what is "adequate" safety information so as to achieve "balance". The intention of the addition to Section 1.1 is to emphasise that there must be "adequate" safety information to balance claims with respect to efficacy or any other promotional claims.

The Code of Conduct Committee (the Code Committee) is concerned by promotional materials that heavily emphasise the efficacy and comparative benefits of a product with little, or sometimes no information about safety of the product. Thus, in a multi-paged detail aid or e-detail aid, you would expect to see some specific safety information included. For a secondary advertisement (for example) where there is a single claim, the reference to the primary advertisement in which the Minimum PI appears might be sufficient to provide "adequate" safety information.

The question of balance also depends on the type of product, the medical condition it is used to treat and whether there are significant safety concerns with the product, which therefore need to be communicated to healthcare professionals.

A company must be able to defend its rationale for how much or how little safety information is included in advertisements and other forms of promotional material.

Section 1.2 Substantiating Data

Section 1.2.1 Provision of Substantiating data

This section affirms that in response to a reasonable request, companies must provide healthcare professionals and members of the industry with supporting evidence. In all but exceptional circumstances the provision of this data should take place within 10 working days of the request. This requirement covers any "data on file" or "in press" material that a company may reference in support of claims.

Companies should be aware that by referencing "data on file" or "in press" material they commit to further supplying that material under the requirements of this section if requested.

Section 1.2.2 Levels of Substantiating Data

This section relates to the level of substantiating data needed to support medical or promotional claims. Note that these provisions are in addition to those of Section 1.1 of the Code. This section describes the types of issues companies should consider when assessing whether the evidence they have is sufficient.

To ensure that readers can be certain that claims are based on appropriate evidence, the quality of the data used to support a claim is paramount. The Code Committee considers that any claim which will significantly influence the way a medicine is prescribed or dispensed should be supported by the highest level of evidence available and consistent with the body of evidence and the Product Information. For example, a comparative claim stating that one product is more efficacious or better-tolerated than another must be supported by evidence that would not leave the reader in any doubt regarding the superiority of the product.

The level of evidence that is appropriate to support a claim will vary according to both the claim being made and the body of evidence. The nature of the study should be made clear to the reader.

The Code Committee and Appeals Committee require that they be provided with substantiating data and will rigorously review these data to ensure that they are of sufficient quality and weight to support the claims being made. The inclusion of a member of the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT) and the other healthcare professionals independent of the pharmaceutical industry as permanent members of the Committees greatly assist in determining whether the evidence provided is sufficient to support the claims made.

The Code or Appeals Committees will not find any substantiating data or reference in breach of the Code. Rather, a promotional claim within an advertisement may be found in breach because the data were inadequate to substantiate the claim.

Companies have a responsibility to update their promotional and educational materials to reflect the availability of new data or emerging evidence while remaining consistent with the approved Product Information.

In relation to the currency of substantiating data, it should be noted that companies may support claims with data that are not referred to in a product's Product Information. However these data must not conflict with the Product Information. The Code Committee has commented that where there is new evidence about a product that may not be consistent with its Product Information (for example, through suggesting a significantly higher level of efficacy or tending to deny the basis for a contraindication or precaution), such data should not be used to support promotional claims. The Committee would expect a company to submit the new data for evaluation in support of an application to update its Product Information, following which the new data could then be relied upon for promotional purposes.

The Code and Appeals Committees would prefer promotional items to note when a company has made a financial contribution to a study that is relied on as substantiating data.

Hierarchy of evidence

The Code Committee uses a hierarchy of evidence when considering complaints against medical or promotional claims, to determine whether the substantiating data provided meets the requirements of this section. A hierarchy of levels of evidence was published by the NHMRC in 1999 in *A guide to the development, evaluation and implementation of clinical practice guidelines* http://www.nhmrc.gov.au/publications/synopses/cp30syn.htm

More recently NHMRC published an updated document which provides an expanded hierarchy of levels of evidence: *NHMRC levels of evidence and grades for recommendations for developers of guidelines, December 2009*

http://www.nhmrc.gov.au/_files_nhmrc/file/guidelines/developers/nhmrc_levels_grades_evidence_120423.pdf

Table 3 of this NHMRC document provides the expanded NHMRC Evidence Hierarchy and associated explanatory notes.

See also: http://www.nhmrc.gov.au/guidelines/resources-guideline-developers

Other useful publications can be accessed from the NHMRC website at:

- How to use the evidence: assessment and application of scientific evidence
- http://www.nhmrc.gov.au/guidelines/publications/cp69
- How to put the evidence into practice: implementation and dissemination strategies
- http://www.nhmrc.gov.au/guidelines/publications/cp71

The level of evidence that is appropriate to support a claim will vary according to both the claim being made and the body of evidence. Although observational studies are level III-3 in the NHMRC Evidence Hierarchy they may represent the highest level of evidence available. For example, when there is no controlled long term treatment data, the most relevant and highest available level of evidence could be from observational data and this data could be used to substantiate a claim. The nature of the study should be made clear to the reader. The decision to use an observational study should be considered on a case by case basis with consideration given to the quality of the observational study and the type of claim.

Abstracts and posters

The Code Committee considers that any claim which will significantly influence the way a medicine is prescribed or dispensed should be supported by the highest level of evidence available and consistent with the body of evidence and the Product Information. Therefore, the Committee considers that in general, abstracts and poster presentations that have not undergone significant peer review and/or have not been accepted for publication in peer reviewed journals are insufficient to provide the sole supporting evidence for a promotional claim. This does not mean that these data sources cannot be used at all. However, they cannot be relied on as the sole support for claims which will have a significant influence on the way a medicine is prescribed or dispensed.

An example of where it may be acceptable to use the abstract or poster as the basis for a promotional claim, is where a clinical study has undergone peer review through evaluation by the Therapeutic Goods Administration (TGA) and has been included in the Product Information, but has not yet been published other than as an abstract or poster. Additionally, if the data presented in the abstract or poster is consistent with other published peer-reviewed papers, if it further extends or supplements other observations and identifies no contradictory evidence, this would further support the acceptability of the use of the abstract or poster. Companies should make it clear (in the citation) that the claim is referenced to a poster or abstract. Companies should use the primary reference or approved Product Information in addition to the referenced abstract or poster.

Companies have requested advice on whether they could use a conference presentation as substantiation for a promotional claim. The Code of Conduct does not refer to conference presentations as a form of substantiating data. Whilst a presentation might include more information and detail than an abstract or poster, a presentation is unlikely to have been subject to rigorous peer review. Therefore, it is recommended that a conference presentation be treated as equivalent evidence to an abstract or poster presentation and not used as the sole evidence to support a claim. When used as a secondary reference, companies should make it clear (in the citation) that it is a conference presentation.

The Code states that all claims must be current, accurate and balanced and be able to be substantiated with appropriate supporting data at the time the claims are published. That is, publication of a supporting study in a peer reviewed journal at some time after publication of the claim is not a defence for the use of the relevant poster or abstract to support the claim.

Secondary Endpoints and post-hoc analyses

When reviewing previous complaints, the Code Committee has been particularly concerned that if the primary endpoint of a study was not met and a claim is based on a secondary endpoint or post-hoc analysis, companies should make it clear to a reader that the primary endpoint of the relevant study was not met.

Section 1.2.2 of the Code gives more specificity about the use of these claims. It is recognised that it is not appropriate to prohibit the discussion of these endpoints as they often provide good insight into a product's efficacy and safety. If the primary endpoint/s was met, qualification may not be required. However, the Code makes it clear that if a claim is based on a pre-specified secondary endpoint where the primary endpoints in the study are not met, the claim must:

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

Any post-hoc analyses must be clearly identified, used in context and appropriately qualified.

It may be acceptable that in the case of an appropriately designed and conducted randomised controlled trial stopped early due to benefit on a non-primary outcome crossing a pre-defined threshold; this result may be communicated without reference to the primary endpoint. However further qualification may still be required to ensure a reader fully understands the context of the claim.

Representation of data in tables and graphs

Where a table or graph has been adapted from other sources, companies are encouraged to ensure that the adaptation does not alter the conclusions of the original paper and that the graph or table is clearly identified as being adapted from another source. The adapted table or graph should be an accurate reflection of the original findings and should be clear and not confusing to the reader or intended to disguise the results.

Where a tabulated or graphical representation of data based on different kinds of analyses is presented in a comparative manner, the different methods of analysis must be clear to the reader. For example, where results from an intention to treat analysis are compared with a retrospective sub-group analysis it must be clear to a reader that the analyses are based on different methodologies and interpreted on that basis.

The Code and Appeals Committees have been of the view that the juxtaposition of data from different studies within one graph or table in detail aids or items of promotional material in a manner that implied the data related to head-to-head studies was misleading and should not be used. When graphs or tables from different studies are juxtaposed as a result of layout, the graphs/tables should be accompanied by qualifying text of sufficient detail to allow the reader to understand the differences between the respective datasets.

Section 1.3 False and Misleading Claims

The purpose of this section of the Code is to ensure that claims and statements made by companies are current, accurate, balanced and not mislead either directly, by implication or by omission. This relates to promotional and medical claims, including taglines, to healthcare professionals and all information and graphical representations provided to healthcare professionals or members of the general public.

All claims must be referenced. Type size for references in printed promotional materials must be not less than 1.5 mm as measured by the font's lower case "e". If the text is printed in 'all capitals' the type size of the capital

letters should be the same as a capital letter that would appear in ‘sentence case’ where the lower case ‘e’ is 1.5 mm in height.

Reference citations should be in a style that will allow the reader to identify and readily locate the reference, such as Vancouver style.

Comparative advertising or promotional material must always meet all the requirements of Sections 1.3 and 1.8 of the Code.

When comparative claims are made, the Committee requires unequivocal evidence that the comparison meets the requirements of this section. Care should therefore be taken to ensure that any comparative claims are both supported by appropriate evidence and reported accurately. Given the possibly significant impact of comparative claims on prescribing practices, the Code requires a higher level of evidence to support such claims. See also Section 1.8 of these Guidelines.

The following are examples of situations where material may be considered to be false and/or misleading and therefore in breach the Code. This list is not all inclusive and is based on the experience of the Code Committee.

a) Literature references or quotations derived from a study or studies and citations of individual opinions which are significantly more favourable or unfavourable than has been demonstrated either within the study, or more likely from the body of clinical evidence or experience. 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.

b) Information or conclusions from a study that is clearly inadequate in design, scope or conduct to furnish support for such information and conclusions.

c) Citation of data previously valid but made obsolete or false by the evaluation of new data.

d) Suggestions or representations of uses, dosages, indications or any other aspect of the Product Information not approved by the TGA.

e) Shortening an approved indication (for example, in a by-line) so as to remove a qualification or limitation to the indication.

f) Use of animal or laboratory data as sole evidence to support a promotional claim. It should be noted that 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 lower case ‘e’ for printed materials. The original statement and the qualifying statement must be linked by use of a readily identifiable asterisk or a similar symbol.

g) Presentation of information in such a manner, for example type size and layout that to the casual reader could produce an incorrect perspective. The type size used for qualifying statements in printed materials must not be less than 3 mm as measured by the height of the font’s lower case “e”. The qualifying statement must appear directly below or adjacent to the claim using a type size not less than 3 mm based on the lower case ‘e’ for printed materials. The original statement and the qualifying statement must be linked by use of a readily identifiable asterisk or a similar symbol.

   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.

h) Statements made about a competitor product, particularly negative statements, not balanced with corresponding information about the product being promoted.

i) Shortening the title of graphical representations reproduced from literature in a manner that alters the original author’s meaning.

j) Use of overseas Product Information to support a claim where that information is inconsistent with the Australian Product Information.

k) Literal or implied claims that a parameter, contraindication, cautionary statement, adverse reaction or limitation on a claim in the Product Information, is not cause for concern.

l) Lack of substantiation of claims not of a medical or scientific nature. It includes information or claims relating to marketing factors such as pricing and market share. Care should be taken when extrapolating prescribing practices from sales data.

Use of in vitro, laboratory or animal data

Care should be taken when using these data (See item (f) above). The Code requires that if these data are used, they are clearly identified by a qualifying statement which must appear immediately below or adjacent to the claim. It is important that there be no inappropriate suggestion, either intentionally or by omission, that would lead a reader to infer some clinical effect based on non-clinical data. It may be appropriate to use a qualifying statement such as "Laboratory/in vitro/animal data does not necessarily predict human clinical effect". Companies are encouraged to refrain from placing these data and clinical claims in close proximity or, in some circumstances, on the same page as this may be misleading.

Item (f) relating to Section 1.3 should not be read as prohibiting the use of animal, in vitro or laboratory data as substantiation for claims that cannot be proven by any other mechanism. These characteristics, with any limitations, would also be reflected in the approved Product Information for these products.

The Code Committee has also expressed concern at the use of qualifying statements such as "Clinical efficacy not yet established" as a qualifying statement for non-clinical data. This qualifier inappropriately infers that a clinical effect may be established at some time in the future, which cannot be substantiated.

Using Taglines

Companies should note that promotional taglines, similarly to any other promotional claim, must comply with all provisions of Section 1. The test will be whether the tagline makes an implicit or explicit claim and, if it does, whether there is sufficient evidence to support such a claim. Also refer to Section 1.8 of these Guidelines.

A company must make a decision as to the promotional nature of the tagline and ensure that it is appropriately referenced and qualified.

Qualifying Statements

A qualifying statement is a phrase or statement that is linked to a claim or tagline which modifies, limits, or restricts the claim or information represented diagrammatically. A qualifying statement should assist a reader to correctly interpret the information presented. Usually a qualifying statement will be linked to a claim or tagline through a superscript symbol such as an asterisk or similar device. The citation of the reference publication from which the claim, statement or diagram is sourced is not a qualifying statement; it is a reference.

Figure 1 in these guidelines provides a decision tree to assist companies to determine whether a qualifying statement is required.

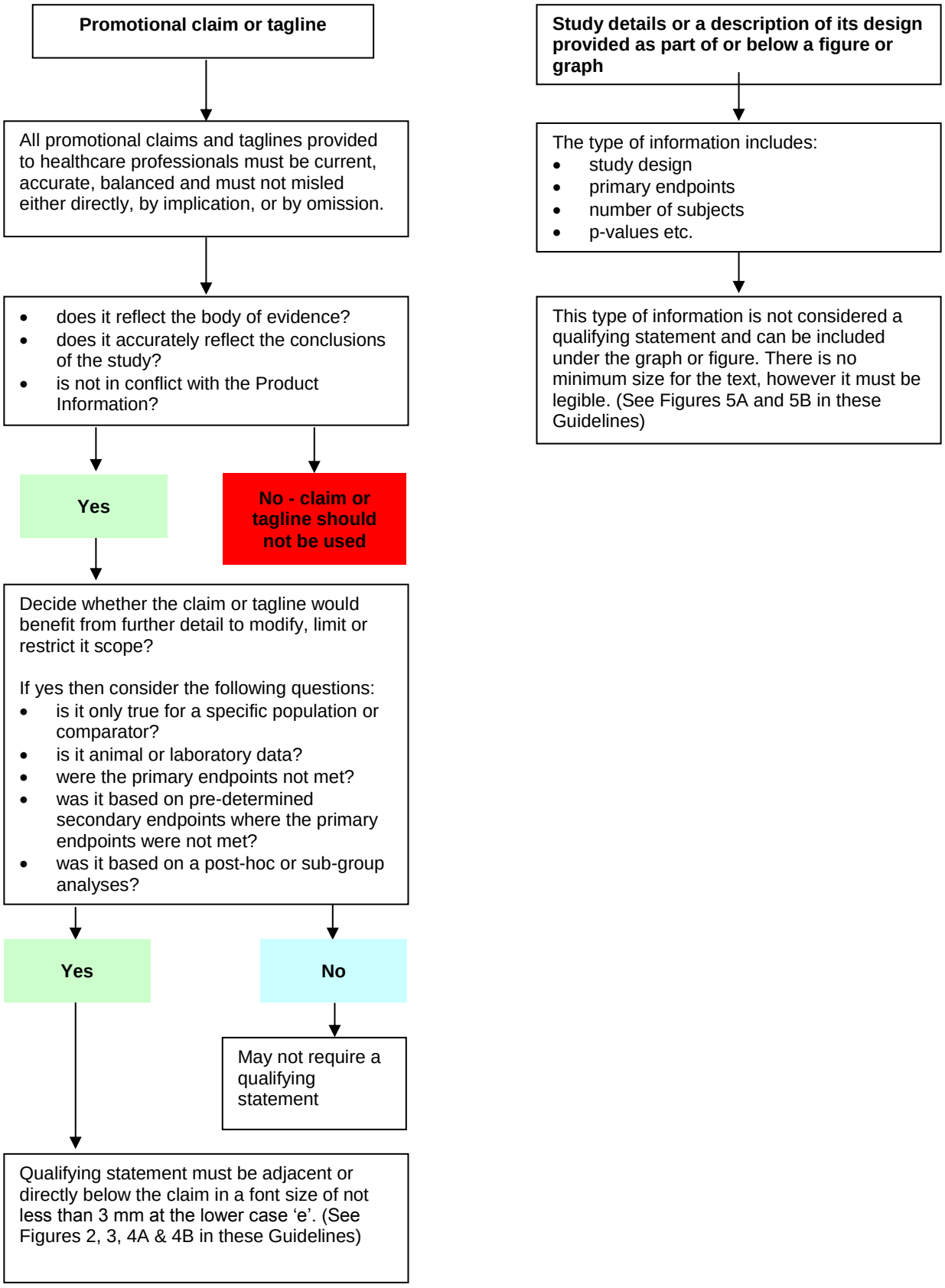
The Code requires all qualifying statements, including the identification of the use of animal or laboratory data to support a claim, to be in a font size of not less than 3 mm based on the lower case 'e' for printed materials and be placed directly below or adjacent to the relevant claim. If the text is printed in 'all capitals' the type size of the capital letters should be the same as a capital letter that would appear in 'sentence case' where the lower case 'e' is 1.5 mm in height.

By way of example:

- A qualifying statement for a single claim in an item of promotional material must appear immediately below or adjacent to the claim, irrespective of where the claim appears on the page. It may not be placed at the bottom of the page or in a side panel, or following other text or claims that are placed below the claim requiring qualification, or below a graph or figure that appears below the claim. (See Figures 2 and 3 in these Guidelines)
- One or more qualifying statements associated with a short list of dot point claims or statements may be placed together immediately below or adjacent to the dot point list. Companies should ensure that the grouping of several qualifying statements together with different symbols linking each qualifier with the relevant statement is not confusing simply because of the number of qualifying statements; overuse of qualifying statements may be as misleading as not using any qualifying statement. (See Figures 4A and 4B in these Guidelines)
- A qualifying statement associated with a figure or graph should be placed immediately below or adjacent to the figure or graph. A qualifying statement may be included within the figure or graph if this does not obscure the figure or graph and assists a reader to easily find any qualifying information to assist with the correct interpretation of the information presented. (See Figures 5A and 5B in these Guidelines)
- Care should be taken in the use of abbreviations that are not well recognised.

There is no limit on the number of qualifying statements that may be used with a claim. The requirement for qualifying statements to be adjacent or immediately below a claim naturally limits the number of qualifying statements. However, companies should consider the validity of a claim if numerous qualifying statements are required.

FIGURE 1: WHEN IS A QUALIFYING STATEMENT REQUIRED?



Figures 2 to 14C in these Guidelines provide guidance on the size and positioning of qualifying statements in print advertisements and printed promotional material.

The advertisements and extract from a detail aid contained in these Guidelines use a fictional pharmaceutical company and product. PharmaMed is not a functioning pharmaceutical company. XampleStat and BetterStat are not registered therapeutic goods.

The examples are for guidance on the size and positioning of references, study data and qualifying statements.

The claims are examples and may not be appropriate for use in all situations.

When these Guidelines are reproduced in some print formats the advertisements and extract from the detail aid may not be an exact replica of the page or font size.

A company must consider all claims and make an informed decision on whether qualification is required. These Guidelines cannot provide examples of all scenarios.

The terms ‘0 kerning’ and ‘auto leading’ are terms used by graphic designers. ‘0 kerning’ is the space between characters and ‘auto leading’ is the distance in points between lines of text.

The Code does not mandate the inclusion of unique identifiers/job numbers on items of promotional material; however such identifiers/numbers provide a company with a system for identifying promotional materials. These may also be useful following a decision of the Code of Conduct Committee which requires an item to be withdrawn. Job numbers are included in these example advertisements. Note that the job number should be separate and distinct from the (mandatory) date the item was prepared or last reviewed.

FIGURE 2: EXAMPLE OF A PRIMARY ADVERTISEMENT WITH A REFERENCED CLAIM AND QUALIFIED TAGLINE

FIGURE 3: EXAMPLE OF A PRIMARY ADVERTISEMENT WITH A CLAIM AND QUALIFYING STATEMENTS

FIGURE 4A: EXAMPLE OF A PRIMARY ADVERTISEMENT WITH A MULTI-LEVEL CLAIM AND QUALIFYING STATEMENT

FIGURE 4B: EXAMPLE OF A PRIMARY ADVERTISEMENT WITH A MULTI-LEVEL CLAIM AND QUALIFYING STATEMENT IN THE WRONG LOCATION

FIGURE 5A: EXTRACT FROM A MULTI-PAGE DETAIL AID – STUDY DETAILS, LOCATION OF "NOT SIGNIFICANT" WITHIN GRAPH

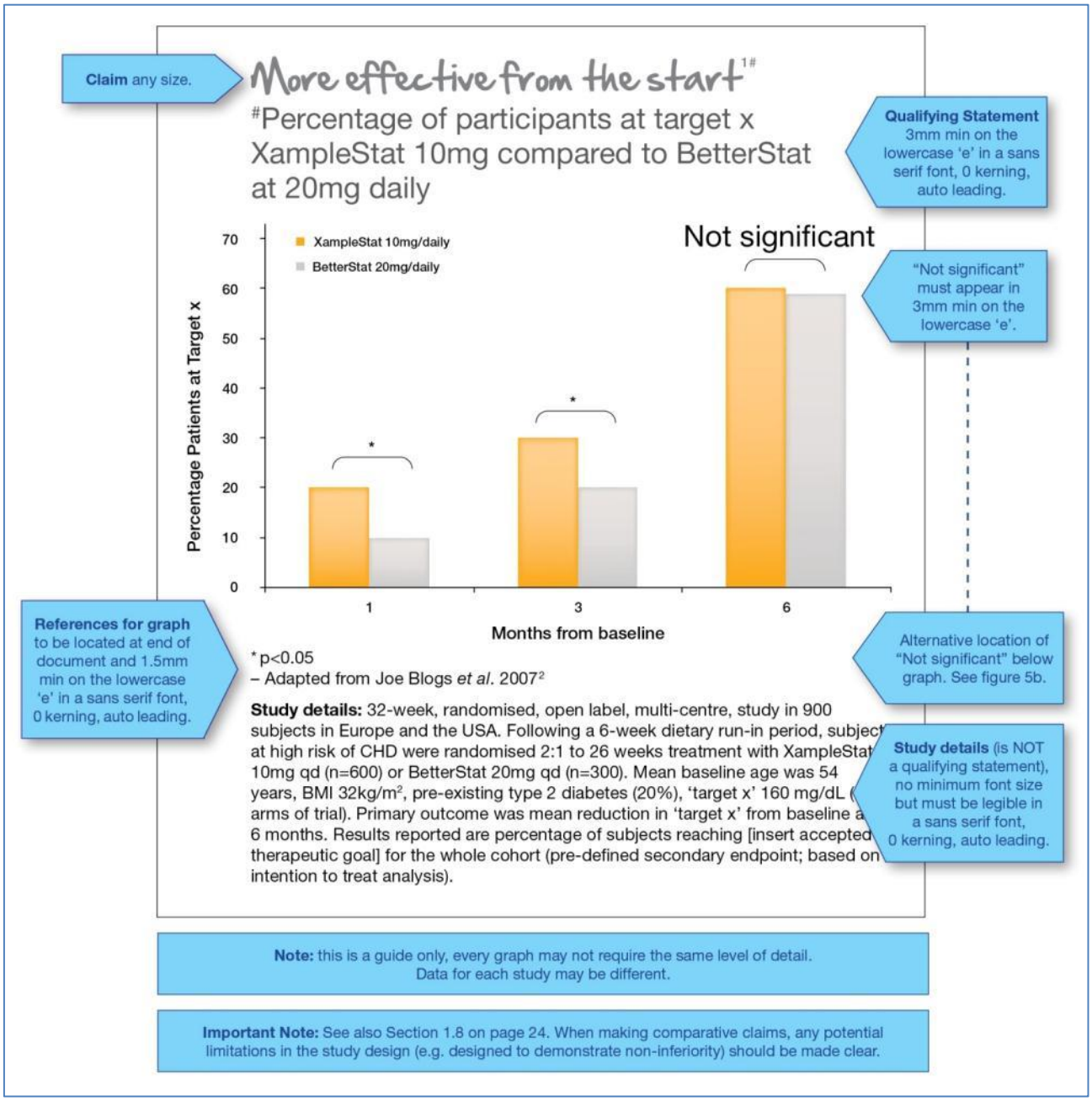
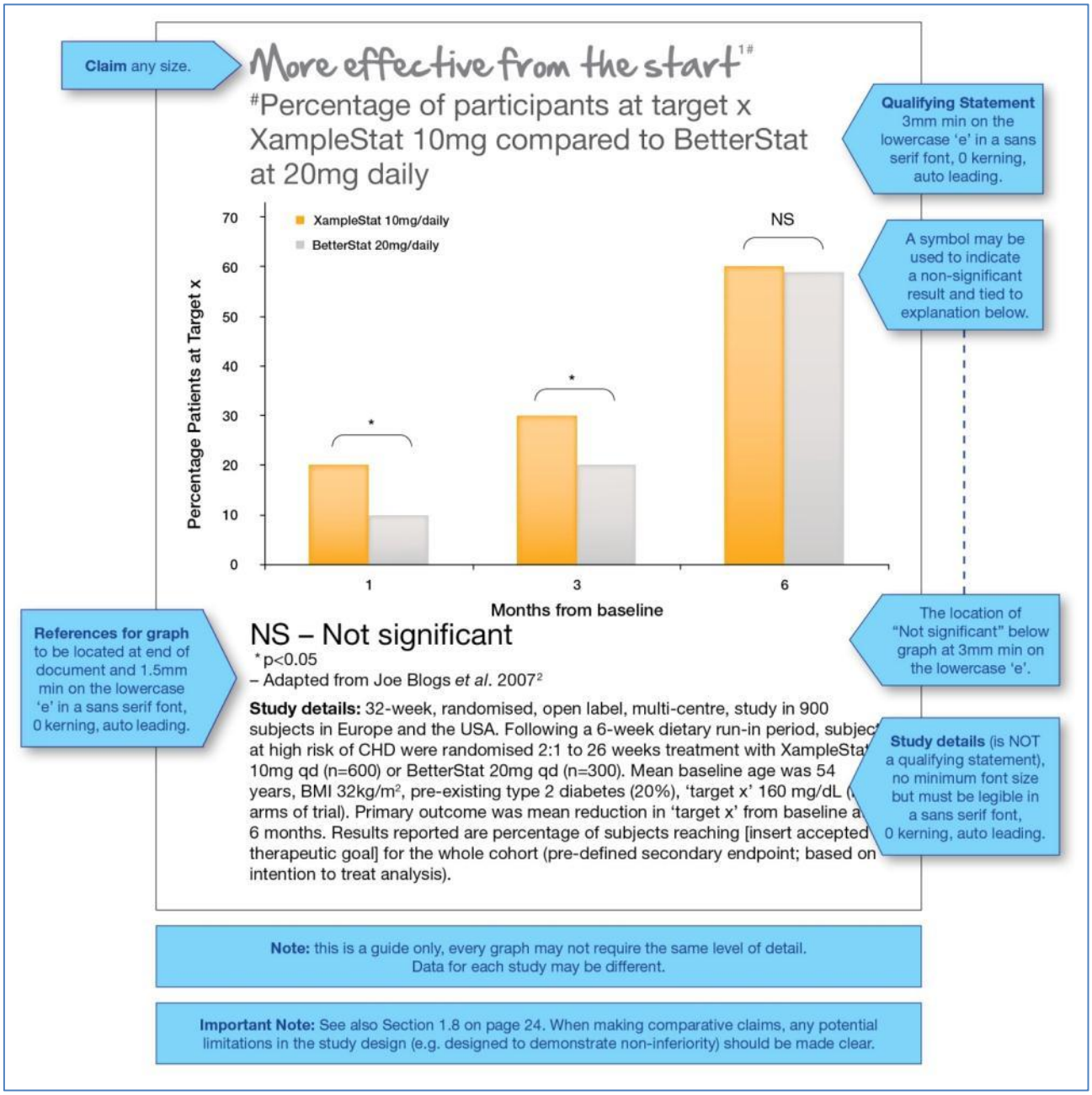


FIGURE 5B: EXTRACT FROM A MULTI-PAGE DETAIL AID – STUDY DETAILS, LOCATION OF "NS" WITHIN GRAPH AND EXPLANATION "NS - NOT SIGNIFICANT" BELOW GRAPH



Section 1.4 Unapproved products and Indications

(See also Sections 4.1, 9.4.1 and 9.6 of these Guidelines)

The Code recognises that valuable peer education is provided by healthcare professionals giving presentations at company-sponsored educational meetings.

The provisions in the Code relating to avoiding the promotion of unapproved products or indications are not intended to prevent the legitimate exchange of scientific and medical information between healthcare professionals or the presentation of independent clinical opinion.

Section 1.4 of the Code reiterates that companies must not promote an unapproved product or an unapproved indication. It is an offence under section 22(5) of the *Therapeutic Goods Act 1989 to* advertise a therapeutic good for indications other than those entered in the Australian Register of Therapeutic Goods for that therapeutic good.

Registration of a new product/indication

Under the Therapeutic Goods Act 1989 (Cth) s 3, "supply" includes:

a) supply by way of sale, exchange, gift, lease, loan, hire or hire-purchase; and

b) supply, whether free of charge or otherwise, by way of sample or advertisement; and

c) supply, whether free of charge or otherwise, in the course of testing the safety or efficacy of therapeutic goods in persons; and

d) supply by way of administration to, or application in the treatment of, a person.

An "advertisement", in relation to therapeutic goods as defined in the Therapeutic Goods Act 1989 (Cth) and the Therapeutic Goods Advertising Code 2007, 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 Section 1.4, "Where a company has been formally advised by the TGA that a product has been entered on the Australian Register of Therapeutic Goods (ARTG)" means that the TGA has provided a registration number to the company and the product is included on the Australian Register of Therapeutic Goods (ARTG). The Certificate of Registration provided to the sponsor company shortly after the listing on the ARTG will reference the date of inclusion on the ARTG. This would also apply to the registration of a new indication, formulation or dosage. Once the product is included on the ARTG a company may commence advertising. A company should also consider whether supply can be assured before advertising the product.

Field-based Medical Personnel

It is not possible to set out the roles of field based medical personnel in detail as these vary from company to company. A general description of the role might be "to provide a means of exchanging medical and scientific and economic information with healthcare experts". Such roles could include, but not limited to:

- responding to unsolicited, specific, individual requests for information from health professionals and/or appropriate administrative staff,
- exchange of medical and scientific information during the development of a medicine, following up adverse drug reaction reports,
- identifying investigators for clinical trials,
- information gathering from certain groups such as key opinion leaders, budget holders etc,
- responding to enquiries from health professionals wishing to run their own studies,
- providing more detailed information on registered products and registered indications than sales representatives,
- responding to requests for more information in relation to budgetary implications of the introduction of new products or new indications for existing products,
- training company staff and providing disease area information.

The activities of field based medical personnel related to Clinical Research fall outside the scope of the Code. When field based medical personnel are working on Clinical Research related activities they should observe a company's internal procedures and other guidelines and policies that govern good conduct in clinical research.

The overall governance of field based medical personnel should be the responsibility of the medical director or similar, irrespective of reporting lines, rather than the commercial side of the company. The differences between field based medical personnel and a sales representative should be obvious to healthcare professionals. Field based medical personnel should be appropriately qualified and trained. They must be fully conversant with the requirements of the Code and these Guidelines.

Where field based medical personnel are providing information on unapproved products or subjects not covered by the Product Information, they must be able to demonstrate that they are responding to unsolicited, specific, individual enquiries from healthcare professionals. It is advsiable that companies have in place a method for documenting these requests for information on unapproved products or subjects not covered by the Product Information as an enquiry received by the Medical department, for example, database capture or file notes.

Materials for field based medical personnel to use when responding to unsolicited enquiries on unapproved products or subjects not covered by the Product Information, such as presentation materials, must be accurate, not misleading and must not have the appearance or tone of promotional material. Materials should be selected and/or prepared by the company medical department and tailored to the enquirier's specific information request.

Advance Notification of New Products or Product Changes

Health authorities, health boards and their equivalents need to estimate their likely budgets two to three years in advance in order to meet financial reporting requirements. Therefore, there is a need for these organisations to receive advance information about the introduction of new medicines, or changes to existing medicines, which may significantly affect their level of expenditure during future years. At the time this information is required, the medicines concerned (or the changes to them) will not be registered by the TGA (although applications will usually have been made). It would therefore be contrary to the Code for them to be promoted. Information may, however, be provided on the following basis:

- the information must relate to:
    - a product which contains a new active substance, or
    - a product which contains an active substance prepared in a new way, such as by the use of biotechnology, or
    - a product which is to have a significant addition to the existing range of approved indications, or
    - a product which has a novel and innovative means of administration.
- the information should be directed to those responsible for making policy decisions on budgets rather than healthcare professionals who would prescribe.
- the information must make clear if the new medicine or change to an existing medicine is the subject of a marketing application in Australia.
- the information must be factual and limited to that which is sufficient to provide an adequate but succinct account of the product's properties. Other products should only be mentioned to put the new product into context in the therapeutic area concerned. No comparative information should be provided.
- the information should not include mock ups or drafts of Product Information or patient information documents.
- if requested, further information may be supplied or a presentation given.

Company Medical Information websites/mobile applications

Under the Therapeutic Goods Act 1989 (Section 22, (5)) it is an offence to advertise/promote a therapeutic good that is not registered on the ARTG and it is an offence to advertise/promote an indication that is not included in the registration of the therapeutic good. Companies are permitted to provide information to healthcare professionals on unapproved product and indications only when the request has come to the company in an unsolicited manner. Responses to all such requests must only be prepared by the medical department or by Medical Information services.

The availability of information on unapproved products and indications must not be promoted to healthcare professionals. Company representatives may provide contact details for the medical department, Medical Information services (including Medical Information websites) or forward enquiries on to the Medical Information Department.

Commercial functions, including members of the sales and marketing functions:

- must not proactively inform a healthcare professional that information on unapproved products or indications are available from the company.
- must not enter into any discussions with healthcare professionals regarding unapproved products or indications or the content of Medical Information responses on unapproved products or indications.
- must either refer healthcare professionals requests for any additional Medical Information to the appropriate Medical colleague or the Medical Information department, or provide the healthcare professional with the contact details for these colleagues or departments (or Medical Information websites/mobile applications).

Protected Access

All medical information provided by companies to healthcare professionals must not be accessible by the general public. The Code (Section 2.4.1) requires that websites/mobile applications are password protected or utilise other entry systems such as a provider number.

It is acceptable for access to a Medical information website to be made available via these company controlled websites/mobile applications via a "Medical Information" button or similar. Whilst these company sites may include promotional content, once a healthcare professional has accessed the Medical Information site, it must not contain any promotional content.

Company Medical Information Websites and the requirement that there must be no promotion of unapproved products or indications

In the event that a company's Medical Information website contains information on unapproved products or indications, this website/mobile application:

- must not contain any promotional material/marketing materials/advertisements
- must not promote that information on unapproved products or indications is available

As specified in the Code, *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*

An example of such a disclaimer is:

Unapproved Indication:

> *This document includes information regarding [Product] and [indication or use]. [Product] is indicated for [include approved indications and uses]. [Company name] does not suggest or recommend [Product] for indications/uses other than those listed in the Product Information*.

Unregistered Product:

> *This document includes information regarding [Product] and [indication or use]. [Product] is not registered by the TGA. The efficacy and safety of [Product] has not been established*.

Company Medical Information Websites/Mobile Applications and the requirement that information on unapproved product or indications must be unsolicited

As required by the Code, information on unapproved products or indications contained in a Medical Information website/mobile application may only be accessed by the healthcare professional entering at least two keyword search terms. The Medical Department is responsible for assigning the keywords to the response. To satisfy the requirement that the responses displayed are unsolicited, the keywords assigned to responses on unapproved products or indications:

- must be highly specific to the information contained in the response,
- must be as narrow as possible; broad search terms must not be used,
- may only be available from a drop down list when the term is the name of a registered product,
- auto-suggest/ type ahead or other assisted searching methodology must not be applied to keywords identifying responses to unapproved products or indications.
- It would be permissible to have a drop down list of product names and indications as search terms as long as the list does not contain the names of unapproved products or indications.

The restrictions above do not apply to Medical Information responses or searches for approved products and indications.

An overarching principle for Medical Information websites is that they are a representative collection of responses prepared by the Medical Department in response to enquiries from healthcare professionals.

The Code or Monitoring Committees may ask Companies to provide the keywords assigned to information on unapproved products or indications to assist with their deliberations.

Use of key leader/expert opinions in company promotional materials

In considering complaint 865 (Code of Conduct Annual Report 2007), members of the Code and Appeals Committees were of the view that while it is acceptable for a healthcare professional to express their personal view of a treatment regimen at a conference, once a company translates this view into a company promotional piece and proactively distributes the item to healthcare professionals they must accept responsibility for the content. It is the responsibility of the company to ensure that any promotional material is fully compliant with the provisions of the Code and does not conflict with the Product Information. Waivers or disclaimers will not abrogate a company's responsibility if the material includes reference to off label use of a product.

Section 1.8 Comparative Statements

Company advertising commonly contains comparisons with other products and such comparisons are usually made to show an advantage of the advertised product over its competitor/s. Provided that such comparisons with other products are factual, fair and can be substantiated, they are acceptable under the Code.

The intention of this provision is to prohibit unjustified comparisons in which the product or activities of a competitor are unfairly denigrated.

Any comparison should intend to provide valuable and accurate information comparing products for the benefit of healthcare professionals and their patients. The presentation of a comparative claim should be thoroughly considered; it is critical that the depiction of any comparison is accurate.

It is important to remember that if you are making comparative claims you need unequivocal supporting evidence. The Committee will carefully scrutinise the evidence provided to accompany any comparative claim to ensure it is sufficient to support the comparison being made. This will include a review of the type of evidence provided, for example, an examination of issues such as the protocols of any studies relied on, the primary and secondary results of these studies, the authors, and if/where the study was published (see also Section 1.2 of these Guidelines for further information on supporting evidence).

Care should be taken to ensure that any graphical or visual comparisons between products are accurate and appropriate. For example, a breach of the Code was found by the use of unequal width bars in a bar graph comparing the efficacy of two products, which implied that the results of the comparison were more meaningful for one product than another. Such a graph was considered unfair and misleading and found to be in breach of these provisions of the Code. (see also Section 1.2.2 of these Guidelines for further information on representation of data in tables and graphs)

Section 1.8 of the Code states that "Where a comparative claim relates to a specific parameter, any claims must be clearly identified as pertaining to that parameter." By way of example, if a non-inferiority study is used to support a comparative statement, it should be clear to the reader that the study design was to demonstrate non-inferiority. The appropriate statistical variables for the study design should be clearly stated. This explanatory information would most appropriately be included as part of the 'study details' (see examples in Figures 5A and 5B).

PBS Disclosure Requirements

Background

In the lead up to the 2002 Federal Budget, Medicines Australia discussed with the government ways in which PBS expenditure could be reduced by ensuring prescribers were provided with information regarding the PBS status of medicines. In an effort to assist the government, Medicines Australia agreed to make amendments to its Code of Conduct to require the disclosure of this information in promotional material and by its medical representatives. The amendments to the Code adopted in September 2002 and subsequent Code editions reflect this agreement with the government. The Guidelines do not distinguish between Section 85 and Section 100 listed products. All advertised prescription medicines must comply with this requirement.

The following discussion sets out the requirements as to how this information should be disclosed.

Companies are encouraged to refrain from using PBS prices in a comparative manner as simple comparisons are fraught with difficulty and may ignore complexities such as daily treatment costs, average dose costs or discounting that are not encompassed by the PBS price. Simple comparisons, without adequate explanation or clarification, could be considered misleading.

Section 2.1 Print Media

Primary Advertisements (Section 2.1.1.1), Secondary Advertisements (Section 2.1.1.2) and Short Advertisements (Section 2.1.1.3)

This section requires that various promotional materials include a clear and prominent statement drawing the attention of the reader to any Pharmaceutical Benefits Scheme (PBS) listing and restriction. The following guidelines identify the minimum requirements for the content and layout of this disclosure in promotional material.

If a Secondary or Short advertisement appears in a publication in which a Primary advertisement for the same product also appears and the Secondary or Short advertisement does not include the PBS information, the following text must appear in the Secondary or Short advertisement in a type size of not less than 2 mm at the lower case ‘e’:

“For PBS information refer to Primary advertisement”.

2.1A. General Requirements

These requirements apply to printed advertisements and promotional material:

(i) The PBS disclosure information should be contained within a text box that has a white background and is outlined in black.

(ii) The font used should be either Arial or Universal (not condensed forms) or a similar clear “sans serif” face. (NB fonts corresponding to these may go under different names, e.g. Helvetica.)

(iii) The text should appear in solid black with no half tones.

(iv) The spacing within the text box must make conventional use of upper and lower case type and contain adequate space between any lines and words to ensure easy readability.

(v) The text size should reasonably fill the text box with the minimum size to be not less than 2mm.

(vi) The text box must contain only the PBS disclosure information. No embellishments or other material should be included in this box including pack size, dosage forms, presentations, quantities, number of repeats etc.

2.1B. Wording

Products listed on the PBS without any restrictions

(i) For products listed on the PBS without any restrictions, the following wording should appear in the text box: “PBS Information: This product(s) is listed on the PBS as a (insert the product type of product as identified in the Schedule)”. See example below.

PBS Information: This product is listed on the PBS as a drug for obstructive airway diseases

Products listed on the PBS as a restricted benefit or where an authority is required

(ii) For products with differing formulations where the promotional item covers all formulations all information about those formulations should be included in the text box. Where only one formulation is being promoted the PBS Box need only include information pertaining to that formulation. The same applies for different indications. See example below.

Different formulations where both are promoted example:

PBS Information: Formulation X. Authority required for the treatment of Y
Formulation Z. This product is not listed on the PBS.

Different indications where both are promoted example:

PBS Information: Authority required for the treatment of Y
This product is not listed on the PBS for the treatment of X.

(iii) For products listed on the PBS as a restricted benefit or where an authority is required, and this information is no longer than three lines as they appear in the PBS Schedule, the following wording should appear in the text box: "PBS Information: Restricted Benefit or Authority Required. Insert wording of the restriction or authority requirement". See example below.

PBS Information: Restricted benefit. Symptomatic treatment of osteoarthritis

(iv) For products listed on the PBS as a restricted benefit or where an authority is required, and where this information is longer than three lines as it appears in the PBS Schedule, the following wording should appear in the text box: "PBS Information: Restricted Benefit or Authority Required. Either the statement "Refer to PBS Schedule for full information" or an accurate paraphrase or précis of the PBS restriction". This information also applies to Section 100 products. See examples below.

PBS Information: Restricted benefit. Refer to PBS Schedule for full restricted benefit information.

PBS Information: Restricted benefit. For use in patients that meet the criteria set out in the General Statement for Lipid Lowering Drugs

Products not listed on the PBS

(v) For products not listed on the PBS, the following wording should appear in the text box: "PBS Information: This product(s) is not listed on the PBS". See example below.

PBS Information: This product is not listed on the PBS.

(vi) For products not listed on the PBS but listed on the Repatriation Pharmaceutical Benefits Scheme (RPBS), the following wording should appear in the text box: “PBS Information: This product is not listed on the PBS. For RPBS information refer to the PBS Schedule.” See example below.

PBS Information: This product is not listed on the PBS. For RPBS Information refer to PBS Schedule

National Immunisation Program

(vii) The current National Immunisation Program (NIP) Schedule started on 1 July 2007 and outlines the recommended vaccines by age group which are funded by the Immunise Australia Program. States and territories may choose any combination of vaccines from those listed on the Health Act (1953) Determination 2009 (Immunisation Program – Designated Vaccines) as best suits the needs of geographic and demographic conditions. See example below.

PBS Information: This product is listed on the National Immunisation Program (NIP). Refer to NIP Schedule

(viii) For vaccines listed on the NIP and PBS see example below.

PBS Information: This product is listed on the National Immunisation Program (NIP) Schedule and the PBS. Refer to the NIP and PBS Schedule

(ix) For vaccines on the private market that are not on the NIP schedule please see the example below.

PBS Information: This product is not listed on the National Immunisation Program (NIP) or the PBS.

Streamlined Authority

A large number of PBS-subsidised medicines that require an authority approval before they can be prescribed have a streamlined authority process.

(x) For products listed on the PBS where an authority is required and this information is no longer than three lines as it appears in the PBS Schedule, the following wording should appear in the PBS text box. See example below.

PBS Information: Authority required (STREAMLINED) Insert authority wording

(xi) For products listed on the PBS where an authority is required, and this information is longer than three lines as it appears in the PBS Schedule, the following wording should appear in the PBS text box: Either the statement “Refer to PBS Schedule for full information” or an accurate paraphrase or précis of the PBS restriction. This information also applies to Section 100 products. See example below.

PBS Information: Authority required (STREAMLINED). Refer to PBS Schedule for full authority information.

Highly Specialised Drugs Program

Highly Specialised Drugs are medicines for the treatment of chronic conditions. These drugs are provided for under section 100 of the *National Health Act* 1953 (Cth).

(xii)

PBS Information: This product is listed on the PBS as a Section 100 item Refer to PBS Schedule for full authority information.

Blood Products

While blood products are not scheduled medicines, companies are encouraged to provide the same level of information in their promotional material. See examples below.

(xiii)

PBS Information: This product is not listed on the PBS Please refer to the National Blood Authority for details

(xiv)

PBS Information: This product is not listed on the PBS [Name of product] is funded by the National Blood Authority for (insert indication or patient population) Please refer to the National Blood Authority for details

2.1C. Size

Sizes set out below are the smallest permitted. If need be, the box must be enlarged to accommodate the required text. Please see Section 2.4 Internet for guidance on sizing and placement for PBS disclosure information in mobile media platforms, websites (internet) and e-Newsletters.

Note that a Secondary advertisement can only appear in a publication which also contains a Primary advertisement.

A Primary advertisement must include PBS information included in a text box as described below. If the PBS information is included in a Secondary advertisement rather than referring to the associated Primary advertisement, the PBS information must be included in a text box as described below:

- Full or double page advertisements (such as appear in medical journals for example, Australian Doctor or Medical Observer) or advertisements of A4 size or greater

  The text box must be no smaller than 18 cm2 and must allow text of no smaller than 2 mm. For example, a text box could measure 12 cm x 1.5 cm, 6 cm x 3 cm, 18 cm x 1 cm or 9 cm x 2 cm.

  The size of the text will depend upon the length of the disclosure statement and the size of the text box, but must not be less than 2 mm as measured by the font's letter "e".

- Half page advertisements (such as appear in medical journals for example, Australian Doctor or Medical Observer) or advertisements of size A5 up to A4

  The text box must be no smaller than 15 cm2 and must allow text of no smaller than 2 mm. For example, a text box could measure 15 cm x 1 cm, 5 cm x 3 cm, 7.5 cm x 2 cm or 10 cm x 1.5 cm.

  The size of the text will depend upon the length of the disclosure statement and the size of the text box, but must not be less than 2 mm as measured by the font's letter "e".

- Quarter page advertisements (such as appear in medical journals for example, Australian Doctor or Medical Observer) or advertisements less than A5 size

  The text box must be no smaller than 10 cm2 and must allow text of no smaller than 2 mm. For example, a text box could measure 10 cm x 1 cm, 5 cm x 2 cm, 7.5 cm x 1.33 cm or 8 cm x 1.25 cm.

  The size of the text will depend upon the length of the disclosure statement and the size of the text box, but must not be less than 2 mm as measured by the font's letter "e".

Section 2.1.1.4 Company Commissioned Articles Section

It is recognised that the distinction between company commissioned articles and advertisements can be blurred. Through the use of statements from an independent expert in combination with promotional claims on behalf of the company, the material becomes an advertisement – whether published in a journal or other form such as a newsletter distributed to healthcare professionals by a company representative. Company commissioned articles that contain a promotional claim must comply with the PBS disclosure requirements of the Code and its Guidelines and include Product Information as required by Section 2.1.1.1 or Section 2.1.1.2 of the Code.

Section 2.1.1.5 Reference Manual Advertising Section

For all reference manual advertising in publications such as the *MIMS Abbreviated*, which is greater than a third of a page as measured by the Reference Manual, a text box must appear containing the statement "For PBS Information refer to Section *insert relevant reference manual section"*. The size of the font must be not less than 2 mm measured by the font's lower case "e". See example below.

For PBS Information refer to Section 2(f)

For advertising which is a third of a page or less, companies are encouraged to include a statement advising healthcare professionals of the location of the PBS information within the Reference Manual.

Section 2.1.2 Printed Promotional Material provided to/or used for discussion with healthcare professionals

The size requirements for the PBS disclosure information applying to Primary advertisements also apply to printed promotional material, and text which complies with these requirements should appear at least once in each item of printed promotional material.

PBS and Product Information for items containing small advertisements

Medical telephone message books

The Guidelines Working Group accepted that medical telephone message books and pads were required to retain a duplicate of a message as a record, which is an element of practice accreditation. It was therefore accepted that such telephone message books, which may include advertisements for prescription medicines, may be supplied to healthcare professionals for use in the workplace.

For guidance on the inclusion on PBS and Product Information please refer to Figures 6 and 7and Table 1 in these Guidelines.

Doctors' Desk Sets

A Doctors' Desk Set must not include sticky notepads or tear-off message notepads promoting prescription medicines (either as the equivalent to a brand name reminder or as a short advertisement containing claims). The Desk Set may include advertisements for prescription medicines as a fixed part of the Desk Set (for example as part of the construction of the desk set 'blotting page'). It may include patient aids in the form of a tear off leaflet or notepad, for example an anatomical diagram, which can be used by a healthcare professional in consultation with a patient and possibly given to the patient to take away.

For guidance on the inclusion on PBS and Product Information please refer to Figure 8 and Table 1 in these Guidelines.

Diaries

To be an acceptable item to be given to a healthcare professional, diaries must include significant educational information for the purpose of promoting medical education or assisting clinical practice, such as the inclusion of medical conferences, seminars and meetings.

For guidance on the inclusion on PBS and Product Information please refer to Figures 9 and 10 and Table 1 in these Guidelines.

Calendars/Year Planners

To be an acceptable item to be given to a healthcare professional, calendars and year planners must include significant educational information for the purpose of promoting medical education or assisting clinical practice, such as the inclusion of medical conferences, seminars and meetings.

For guidance on the inclusion on PBS and Product Information please refer to Figure 11 and Table 1 in these Guidelines.

TABLE 1: PBS AND PRODUCT INFORMATION FOR ITEMS CONTAINING SMALL ADVERTISEMENTS

Medical telephone message books	Doctors Desk Sets	Diaries	Calendars/Year Planners
PBS Information			
This text should be clearly distinguishable from any other text and contained within a text box with a white background and black border. For PBS Status go to www.pbs.gov.au	If a Doctors' Desk Set contains a number of small advertisements a reference must be made to the PBS disclosure information. The Desk Set must include a statement to the effect "For PBS information, refer to PBS information which can be found …. (include the location: for example, … on the back page of this desk set."	Each advertisement included within a diary must include the PBS disclosure information. Where the advertisement within a diary is of sufficient size, the PBS disclosure requirements for a Primary advertisement apply (Section 2.1.1.1). Where the diary is of a pocket size, the advertisement must carry a statement to the effect: "For PBS Status go to www.pbs.gov.au".	If a calendar/year planner contains advertisements for prescription medicines a reference must be made to the PBS disclosure information. These items must include a statement to the effect: "For PBS Status refer to PBS Information which can be found …. (include the location: for example), … adjacent to the conference planner, or on the back of this calendar/year planner."
	This statement should appear at least once in a clear and prominent position on the Desk Set. It is not required to be included within each advertisement included in the Desk Set.	This text should be clearly distinguishable from any other text and contained within a text box with a white background and black border.	This statement must appear once in a permanent display position, or alternatively on every page of the item. It is not required to be placed within each advertisement included on the item. The text should be clearly distinguishable from any other text and contained within a text box with a white background and black border.
The text must appear in a font size of not less than 2 mm as measured by the lower case 'e'.	This text should appear in a font size of not less than 2 mm as measured by the lower case 'e'.	This text must appear in a font size of not less than 2 mm as measured by the lower case 'e'.	This text must appear in a font size of not less than 2 mm as measured by the lower case 'e'.

Medical telephone message books	Doctors Desk Sets	Diaries	Calendars/Year Planners
Product Information			
Primary advertisements within these items are not required to include the Minimum Product Information within the body of the advertisement. However, the Minimum Product Information for all advertised products must form a fixed part of the medical telephone message book.	Primary advertisements (those that include a product claim) included within a Doctors' Desk Set are not required to include the Minimum Product Information within the body of the advertisement.	Primary advertisements included within a diary are not required to include the Minimum Product Information within the body of the advertisement. However, the Minimum Product Information for all advertised products must form a fixed part of the diary.	Primary advertisements included within these items are not required to include the Minimum Product Information within the body of the advertisement. However, the Minimum Product Information must form a fixed part of the item.
A clear and prominent statement must be included within the body of each advertisement: "Before prescribing review the Minimum Product Information in the back of this book."	The Desk Set must include clear and prominent statement to the effect: "Before prescribing review the Minimum Product Information which can be found…… (include the location: for example, … in the Product Information booklet in the back pocket or on the back of this publication."	Each advertisement must include a clear and prominent statement to the effect: "Before prescribing review the Minimum Product Information in the back of this book."	Each calendar or year planner must include a clear and prominent statement to the effect: Before prescribing review the Minimum Product Information which can be found …. (include location for example) … adjacent to conference planner, or on the back of this calendar/year planner. This statement need only appear in a prominent position once on the item.
This text must appear in a font size not less than 3 mm as measured by the lower case 'e'.	This text must appear in a font size not less than 3 mm as measured by the lower case 'e'.	This text must appear in a font size not less than 3 mm as measured by the lower case 'e'.	This text must appear in a font size not less than 3 mm as measured by the lower case 'e'.

FIGURE 6: MEDICAL TELEPHONE MESSAGE ADVERTISEMENT – NO QUALIFYING STATEMENT

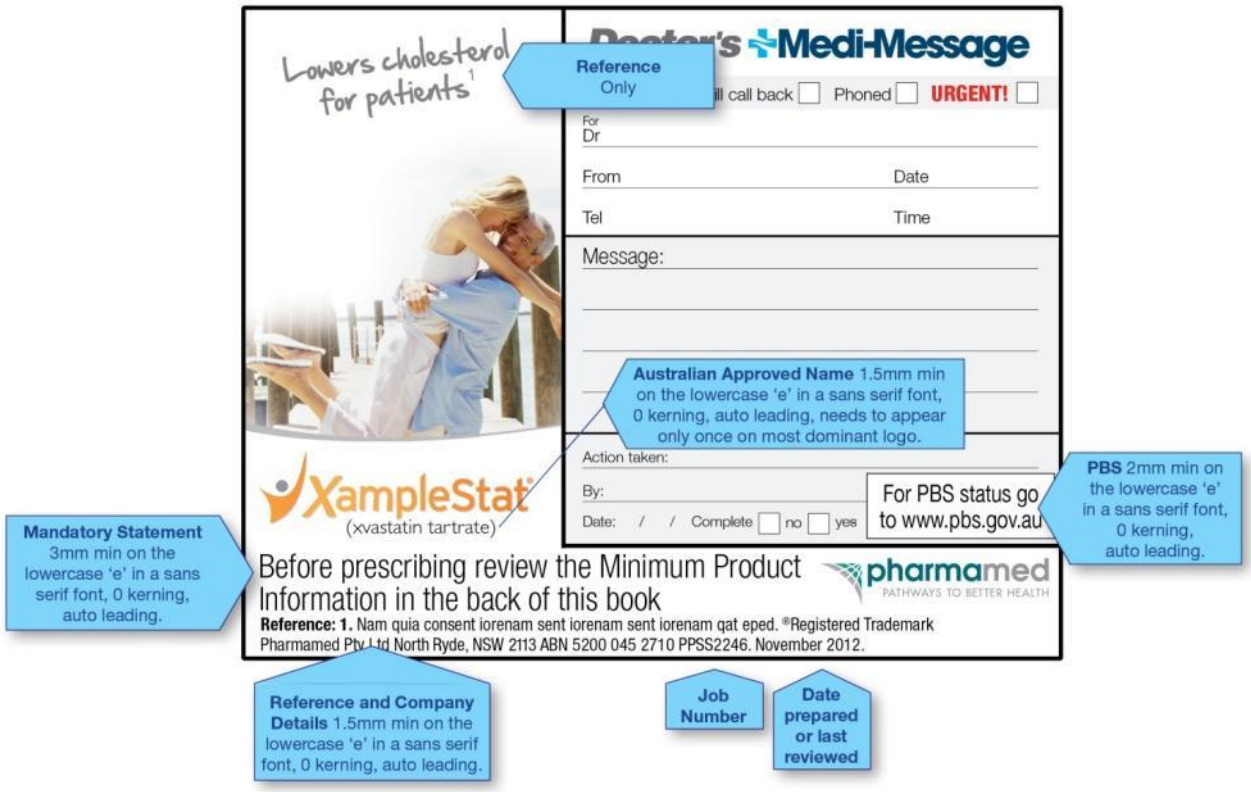


FIGURE 7 MEDICAL TELEPHONE MESSAGE ADVERTISEMENT – WITH QUALIFYING STATEMENT

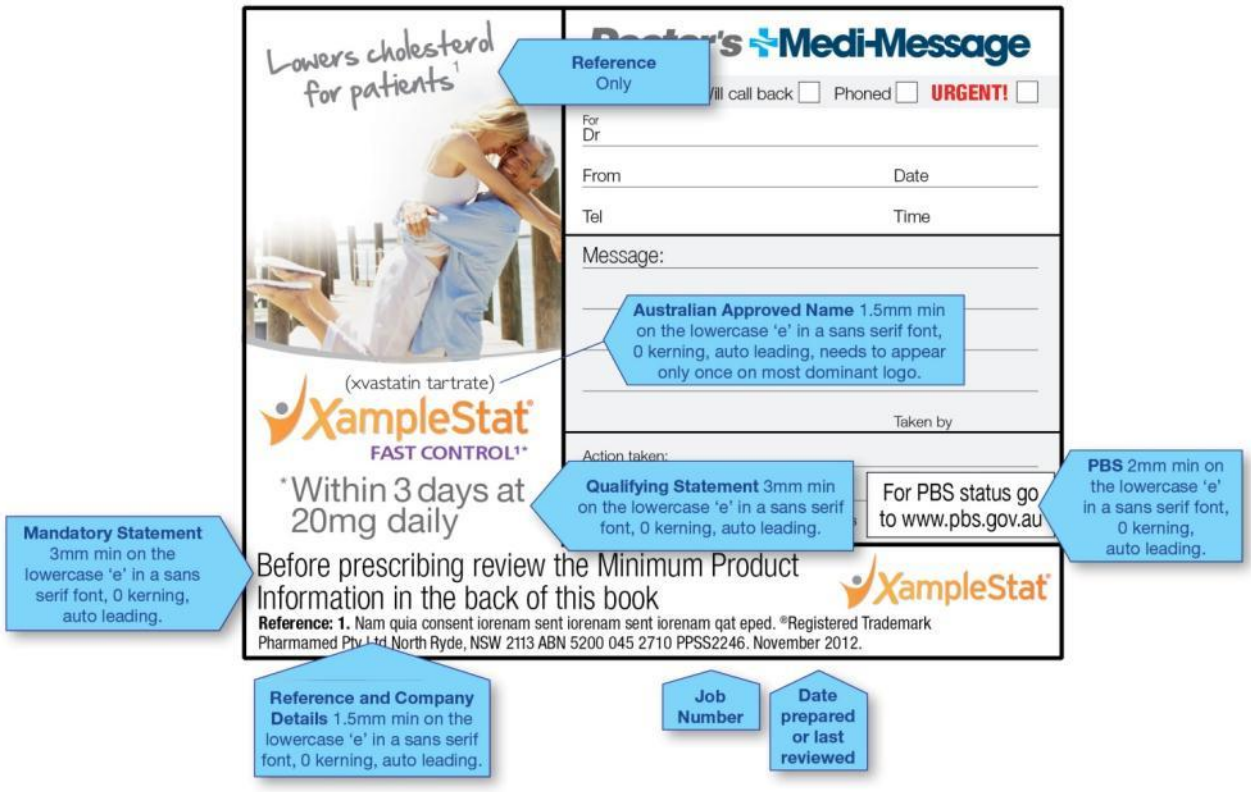


FIGURE 8: DOCTORS DESK SET ADVERTISEMENT

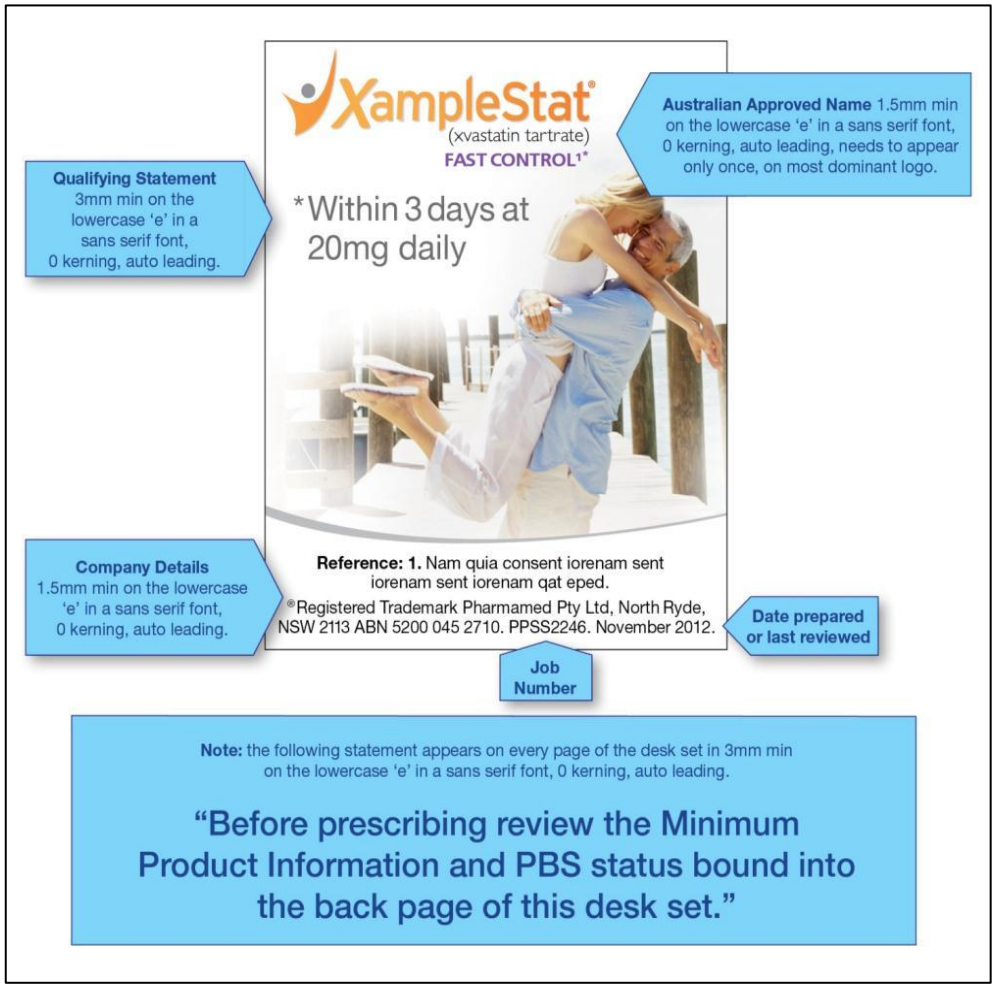
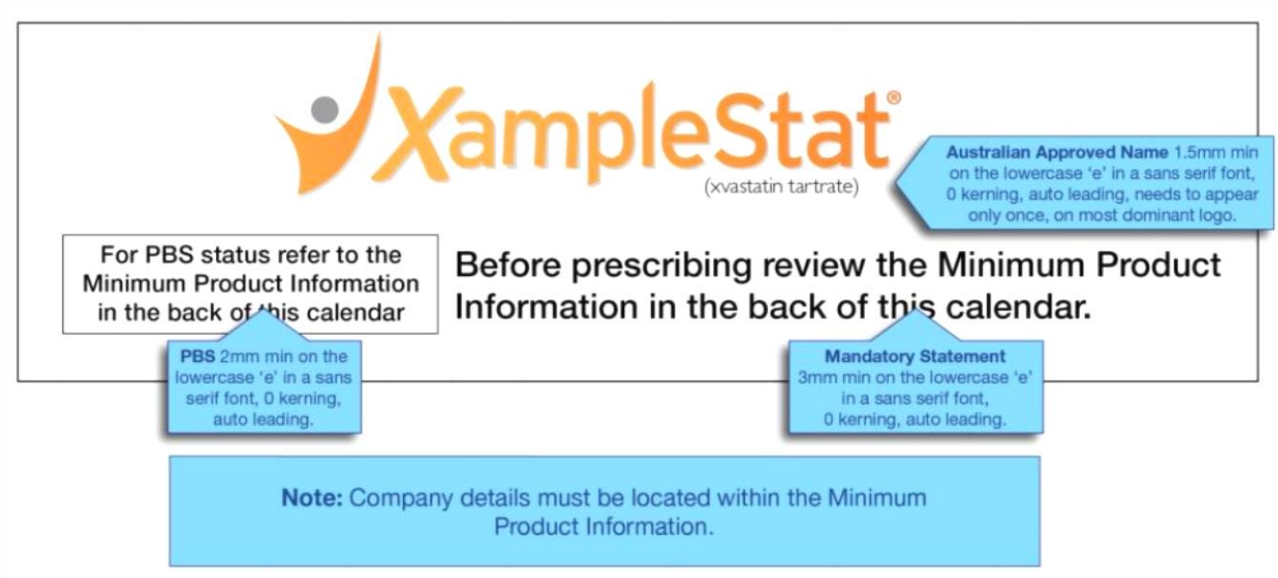


FIGURE 9: DIARY ADVERTISEMENT – NO QUALIFYING STATEMENT

FIGURE 10: DIARY ADVERTISEMENT – WITH QUALIFYING STATEMENT

FIGURE 11: SHORT ADVERTISEMENT FOR CALENDAR



Section 2.2 (Electronic and Audiovisual media including Electronic Detail Aids), Section 2.3 (Restricted Access Television) and Section 2.4 (Internet, social media and eNewsletters) and materials designed for mobile media platforms

These sections provide guidance for non-printed materials. Non-printed promotional materials also are required to include a clear and prominent statement drawing the attention of the reader to any Pharmaceutical Benefits Scheme (PBS) listing and restriction. The following guidelines identify the minimum requirements for the content and layout of this disclosure in these promotional materials.

Note that for advertisements in print media the Code refers to primary, secondary and short advertisements. There is no similar distinction between these forms of advertisements in electronic media. Advertisements in electronic media must include the mandatory information described in Section 2.4.1 of the Code.

Please review other sections of the Code Guidelines for further information on other mandatory inclusions, text sizes etc.

TABLE 2: PBS AND PRODUCT INFORMATION IN ADVERTISEMENTS IN ELECTRONIC AND AUDIOVISUAL, RESTRICTED ACCESS TELEVISION, INTERNET AND E-NEWSLETTERS

Electronic and Audiovisual Media (Section 2.2)	Restricted Access Television (Section 2.3)	Internet, Social media and e-Newsletters (Section 2.4)
Any electronic forms of promotion must be considered in context. That is, "is the information medical education or promotion?" If the material is promotional it must include the PBS listing within the body of the advertisement and a reference to review the Product Information before prescribing. The inclusion of such information does not automatically mean that the material is considered promotional.		
PBS Information		
All PBS listings, including any restrictions, must be listed and/or displayed within the advertisement to allow a prescriber to read 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 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 and understand this information.
The type size used in these media must be such that it allows easy and clear legibility.	The type size used in these media must be such that it allows easy and clear legibility.	The type size used in these media must be such that it allows easy and clear legibility.
Product Information		
A statement to review the Product Information must be included within the body of the advertisement. The Minimum Product Information may be included within the body of the advertisement and/or a direct hyperlink to the Product Information must be included. Where it is not possible to provide a direct hyperlink to the Product Information, the Product Information must accompany the CD.	A statement to the effect: *"Please review Product Information before prescribing. Product Information and substantiating references can be obtained from (insert company name) or by phoning (insert telecaster's phone number)."*	A statement to review the Product Information must be included within the body of the advertisement. The Minimum Product Information may be included within the body of the advertisement and/or a direct hyperlink to the Product Information must be included.

Electronic and Audiovisual Media (Section 2.2)	Restricted Access Television (Section 2.3)	Internet, Social media and e-Newsletters (Section 2.4)
In the case of audio-only material the PBS listing and a statement referring to the Product Information must be audible on the material. *"Before prescribing please review the Product Information. The Product Information accompanies this CD."*		
In the case of presentations which may include promotional claims at a company educational meeting, the Product Information must be offered to the audience on completion of the presentation.		
The type size used in these media must be such that it allows easy and clear legibility.	The type size used in these media must be such that it allows easy and clear legibility.	The type size used in these media must be such that it allows easy and clear legibility.

PBS disclosure Requirements for Medical Education Material (Section 4.1)

Material supplied for medical education must not contain promotional claims and accordingly does not require a PBS disclosure box or Product Information. Any material supplied with educational material and containing a promotional claim must comply with all provisions of the Code in relation to printed promotional material.

PBS disclosure Requirements for Company Representatives (Section 5.8)

This section of the Code requires that company representatives either provide prescribers with information regarding all PBS listings and restrictions, or make reference to this material in printed form when they are making promotional claims regarding a prescription product. It is sufficient for a company representative to verbally advise a healthcare professional of this information, to display the information electronically via a mobile media platform (e.g. tablets), to offer them this information in written form or to refer to a printed source of this information.

The disclosure should be clear and distinct with no attempt to minimise or limit this important information.

PBS disclosure Requirements for Trade Displays (Section 9.6)

To comply with the PBS disclosure requirements for trade displays a prominent statement regarding the PBS status of products being promoted at a trade display must be incorporated on the trade display. This information must be of an appropriate size such that it is easily viewed by the prescriber when visiting the trade display. This statement need only appear once on the trade display. For example, if the trade display consists of three panels, the PBS statement need only appear once provided that it is in the view of all three panels. The PBS information may be on the trade display material, attached (for example, with Velcro®) to the trade display material or free-standing.

The Minimum Product Information is not required on items of printed promotional material for display purposes such as trade display banners, light boxes, panels or posters. However, such materials must include the following statement in an appropriate size that is easily viewed by the prescriber when visiting the trade display:

"Please review Product Information before prescribing. Product Information is available from the trade display."

Section 2 Promotional Material directed at Healthcare Professionals

A company must ensure that third parties (e.g. agencies, publishers and suppliers) are aware of publication dates, the timeframe for publication, and the need for company permission before use of any print or electronic advertisement or promotional material outside the defined time period. It is a company's responsibility to advise the agency, publisher or supplier that an advertisement or item of promotional material must be immediately withdrawn and not used again. Documented evidence of compliance with this should be sought.

Does the Code of Conduct apply to unscheduled or non-prescription medicines?

Companies should be aware of any TGA requirements to follow the Code of Conduct when promoting a medicine or device that may have been included in the marketing approval letters.

Section 2.1 Print Media

Journal advertisements

Care should be taken to ensure that where an advertisement consists of a double sided or multiple page copy, the information contained on each individual page is not false or misleading when read in isolation.

The Code emphasises the requirement that the Product Information or the Minimum Product Information must appear in the body of the advertisement.

If a company advertisement for a new product that is not a new chemical or biological entity (for example a generic or biosimilar medicine) includes a claim, it must fulfil the requirements for a Primary Advertisement. All provisions for Secondary and Short advertisements also apply to a product that is not a new chemical or biological entity.

For details on how to include this information, see PBS Disclosure Requirements in these Guidelines.

Teaser Advertisements

"Teaser advertisements" (an advertisement to healthcare professionals that does not include a product name) should be considered as a whole or in completed sequence so when revealed in their entirety they will not breach the Code. That is, the sequence cannot retrospectively make or imply a claim that cannot be substantiated when all advertisements are read together. No other information is required although a company may include the company name.

Product Announcements directed at healthcare professionals

The information provided by pharmaceutical companies to trade journals for publication in a 'New Products' section must not include promotional claims. The inclusion of a claim will make it an advertisement, which must therefore comply with Section 2.1.1.1 of the Code.

A 'New Product' announcement is usually prepared by a company as final text for publication, but the journal editor might edit the information to meet publication requirements, either abbreviating or adding additional text. A company is responsible for the text it provides to the journal and should retain documentary evidence of what is submitted. A company should assume that the journal may publish the product announcement unedited, without amendment, and ensure that it meets the requirements of the Code when submitted.

Company Commissioned Articles (also known as advertorials)

Independently edited supplements which publish the proceedings of a recognised congress are not considered as Commissioned Articles. The requirements for a Secondary advertisement would apply to these edited supplements where there is a Primary advertisement elsewhere in the publication.

Section 2.1.2 Printed Promotional material directed at healthcare professionals

Minimum Product Information

It is a requirement of the Code that the Minimum Product Information is printed within the body of all items of printed promotional material. This is to ensure that sufficient prescribing information is available to healthcare professionals when reviewing an item of promotional material. This applies to items such as leave behinds, detail aids used for demonstration by a medical representative, retained sales aids, leaflets or any other promotional items which are intended to be provided to a healthcare professional.

In addition, healthcare professionals must also be given immediate access to the Product Information. The Code allows access to be given by including a URL on an item of printed material, which gives direct access to the Product Information, and/or including a telephone number for the company medical information service from which a healthcare professional can request a copy of the Product Information. The URL may be the company corporate website, provided that the landing page includes a product search or product tab to facilitate access to the Product Information. If a paper copy of the Product Information is requested, by telephone, it must be sent within 5 working days. Alternatively the Product Information can be provided with the promotional item.

Date format

In order for the reader to quickly ascertain the currency of any printed promotional piece, the date that the item was prepared or last revised must be included. The format of this date is not specified in the Code; however it must be immediately recognisable as a date. It must also be separate from any job or piece identification number or code on the item. For examples please see Figures 2 - 4 in these Guidelines.

New or reprinted materials distributed after 1 January 2013 must include the date. Materials that were in distribution prior to 1 January 2013 and distributed after that date are not required to be reprinted or overstickered to include the date.

If the content of the piece is reviewed and altered in any way, the re-printed item must show the updated date to reflect the most recent review. If the content of the piece is reviewed, but is unaltered, the date does not need to be updated and the item does not need to be re-printed. However, if the item is reprinted the date may be updated if desired.

Trade Displays

For information with respect to promotional items for display purposes, for example posters, banners or trade display stands, please refer to Section 9.6 in these Guidelines.

Media Releases

By definition if the media release to the medical media is promotional it must include the mandatory items such as the Minimum Product Information and PBS status. For further information please refer to Section 2.8 of these Guidelines.

Conference Handbooks and Satchel inserts

Advertisements included in conference handbooks and conference abstract compilations should be treated in the same manner as Journal advertisements (Section 2.1.1 - Primary, secondary or short advertisements). The rationale for not treating these advertisements as Reference Manual advertising is that the conference publications do not include the Product Information or Minimum Product Information elsewhere within the publication.

Satchel inserts should be treated as items of printed promotional material (Section 2.1.2).

Section 2.1.3 Mailing of printed promotional material to healthcare professionals

This section of the Code covers the requirements for promotional material and patient education material designed for distribution through the postal system or by private means. In addition, each item mailed to healthcare professionals or patients must also comply with the relevant provisions of the Code.

For example, an item of printed promotional material must be compliant with Sections 1, 2 and 2.1.2 of the Code. Material provided as part of a Patient Support Program must comply with Section 17 of the Code.

Exposed mailings such as business reply cards must not include any statements, promotional taglines, pictures or graphics that might be interpreted as promoting a particular prescription medicine to the general public. The use of a product brand name or Australian Approved Name by itself is not considered to be promoting the medicine to the general public.

Statements on envelopes implying urgent attention should be restricted to matters relating to product recalls or important safety information. Envelopes should not be used for dispatch of promotional material if they bear words implying that the contents are non-promotional.

The inclusion of printed full Product Information documents with mailers is not mandatory (see Section 2.1.3 of the Code)

Please also review Section 3.3 of the Code with respect to communicating Changes of Clinical Significance and Boxed Warnings to healthcare professionals.

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

Electronic Detailing

The principles from Sections 1 and 2 of the Code also apply to electronic detailing (“eDetailing” or “eDetail aid”). When writing the recommendations below, the Code Guidelines Working Group made the assumption that such devices included standard size iPads, other tablets, etc. If devices with smaller screens are used, care should be taken to ensure that all text is easily legible from a comfortable distance.

The Code requires that text that is given prominence in printed forms of promotional material, 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.

Care should be taken when each page is viewed that the information is not false or misleading when read in isolation.

Text font, size and colour must be considered to ensure legibility. The resolution provided by different screen sizes should also be taken into account when assessing legibility. All text must be easily visible from a comfortable viewing distance prior to zooming or utilising other similar functions.

Placement of mandatory requirements such as, generic names, p-values, statements of significance etc should follow the same principles as per Section 2.1 of the Code and should be clearly visible on the screen — they cannot only be visible within an animated feature such as a pop up etc.

The Monitoring Committee recommends that where study details or other important information is required for the correct interpretation of a graph or claim, this information should be visible to a reader, rather than being hidden behind a tab that wouldn’t be seen unless clicked upon. If the font size is small, the recommended approach is to allow these study details to easily expand into large size for easy viewing or alternatively, open into a super-imposed dialog box. These methods are preferable to having no information visible.

If an application is intended to be independently navigated through by a healthcare professional and information is included behind a button or tab it must be clear what type of information may be accessed via that tab or button. The information behind the tab or button needs to be intuitively evident, clearly labelled or explained by another means.

It is possible to give emphasis to a specific part of the content/area of a tablet screen through the use of light boxes, stretching/enlarging graphs etc. Content must not be constructed in such a way that there is loss of context by obscuring critical elements, for instance, a claim remains visible but a related qualifier statement, or other descriptive text that provides context, is hidden by a pop-up screen.

Qualifying statements should follow the same principles as Sections 1.3 and 2.1; they should be linked to the relevant claim with a readily identifiable asterisk or similar device. Qualifying statements must appear directly below or adjacent to the claim. A qualifying statement should always be visible when its corresponding claim is on the screen. The qualifying statement must not be hidden by pop ups, if a section of the screen is enlarged, or positioned such that a user has to scroll further down the page to see it.

Other mandatory information such as Product Information, direction to review the Product Information PBS box, boxed warnings, company name and address should all be no more than 2 clicks away from any one screen

(i.e could access via a menu bar) or appear as part of the e-detailer e.g. at the end of each 'chapter/section' of information where an e-detailer is so designed.

The inclusion of the Minimum Product Information is not required if the full Product Information is directly accessible from within the eDetail aid. This is in line with the Code in Section 2 and Table 3 for electronic and audiovisual media and the internet, where the need for the Minimum Product Information is not mandatory if the full Product Information is directly accessible.

Examples of (fictitious) e-Detail aids/Health Apps in a smart phone and tablet device are provided in Figures 13A to 14C in these Guidelines.

Note: electronic presentation of independently produced medical literature/clinical papers through an iPad/tablet e-Detail Aid must be consistent with the same guidance for printed forms as outlined in Section 4.2 of the Code. For further guidance refer to Section 4 — Educational Material Directed at Healthcare Professionals in these Guidelines.

Mobile Media Platforms and the use of Applications (Apps)

A company may wish to provide promotional and educational material to healthcare professionals via an application downloaded on mobile media platforms (eg. iPhone and iPad; Blackberry; Android based smart phones and other tablets). If an App contains promotional material it must only be accessible via a secure App Store/Site or process that is designed to allow access only to healthcare professionals. A mechanism such as a password or other restricted entry system would comply with the requirements of this section. The password to gain access to the App should not be a word that would be easily identifiable, such as the product name.

All material contained on an application directed to healthcare professionals must also comply with Sections 1 and 2 of the Code. This means that the standards applying to items such as advertising and printed promotional material apply to material included on applications for mobile media platforms.

Any electronic forms of promotion must be considered in context. That is, is the information medical education or promotion? If the material is promotional it must include the current PBS listing within the application and a reference to review the Product Information before prescribing; you may either include a direct hyperlink to the current Product Information outside of the application or provide access to the Product Information via a Product Information button within the application.

Companies should also take care when including references or links to other information sites. References to any non-compliant sites that may put the company at risk of being found in breach of the Code should be removed without delay. It must be made clear when the user is leaving the application or being directed to a site that the company is not responsible for and 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.

The type size and graphics used in all application advertisements must be such that allows easy and clear legibility. See Sections 2.2, 2.3 and 2.4 for further information on suitable font sizes and layout. For guidance on the inclusion of PBS and Product Information please refer to Figures 13A to 13D and 14A to 14C in these Guidelines.

A company may wish to provide promotional and educational material to healthcare professionals via Apps. Examples of acceptable Smartphone Apps include, but not limited to: medical dictionaries, access to clinical papers, conference proceedings or planners, and dose calculators. See also Section 2.6 on Brand Name Reminders and items for medical education in these Guidelines.

QR Codes

A company may wish to provide promotional and educational material to healthcare professionals via QR Codes which link directly to applications or microsites. If the destination of these links is visible to the general public (eg. iTunes store, Google Play store or a non-secure website), then a mechanism such as a password protected application/microsite or other entry system would comply with the requirements of this section. The password to gain access to a restricted application/microsite should not be a word that would be easily identifiable, such as a product name.

Section 2.3 Restricted Access Television

The provisions of this Code as they apply to Primary advertisements (Section 2.1.1.1) should be applied to restricted access televisions 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.

Section 2.4 Internet, social media and e-Newsletters

To allow a reader to identify the source of information provided on a website the company name must appear on the home page of any site developed by a pharmaceutical company. This includes sites for healthcare professionals, patients and the general public. In the case of a sponsored site, for example a college, society or health consumer organisation website that has been developed with financial assistance from a pharmaceutical company, in the interest of transparency an acknowledgement that it has been prepared with assistance through an educational grant from [Company X] should be included on the home page of the site.

Section 2.4.1 Company controlled websites for Healthcare Professionals

A company may wish to provide promotional and educational material to healthcare professionals via a website. If this site 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 would 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, such as the product name.

All material contained on a website directed to healthcare professionals must also comply with the provisions of Sections 1 and 2 of the Code. This means that the standards applying to items such as advertising and printed promotional material apply to material included on a company sponsored website.

Any electronic forms of promotion must be considered in context. That is, is the information medical education or promotion? If the material is promotional it must include the PBS listing within the body of the advertisement and a reference to review the Product Information before prescribing. The Minimum Product Information may be included within the body of the advertisement and/or a direct hyperlink to the Product Information must be included. When linking to a PDF of the Product Information or Consumer Medicine Information on a third party site where the viewer cannot navigate away from the page displaying the PI or CMI, a pop-up box warning the reader they are leaving the company controlled site is not required.

Companies should also take care when including references or links to other information sites. References or links to any non-compliant sites that may put the company at risk of being found in breach of the Code should be removed without delay.

Use of healthcare professionals' names on a company website

Medicines Australia has advised companies that they should not include a list of individual doctor's names or clinics on their corporate website or a company developed website for a condition or disease state. In consultation with an independent college or society, and having sought their approval, it may be possible to provide a link to a college or society website where a list of physicians registered with the college or society is made publicly available.

Webinars

A company may wish to hold or moderate a presentation via a webinar. Webinars may be broadcast from a meeting at which a speaker is presenting to an audience or may be broadcast only as a webinar, whereby all audience members are "virtual".

Companies should consider the following when engaging with healthcare professionals via webinar:

- Speaker briefing and slides - The same principles for briefing a speaker and review of slides for face to face presentations should also apply to webinars (See Sections 1.4 and 9.4.1 in these Guidelines).
- Moderation by the company – Based on the nature of the content of the session, companies should make an assessment for the need for moderation. For transparency, a company should consider including a statement alerting the audience if a session will be moderated and include any action that may be taken by the company eg removal of any inappropriate 'material'/posts/questions.
- Delayed broadcast - Webinars may be recorded for later broadcast. It was the Guidelines Working Group's opinion that any time delay afforded a company time to review and edit content to ensure it is compliant with the Code. Broadcasts of third party educational events should follow the same principles as set out in Section 4.1 "Use of conference materials"
- International broadcasts that are made available by the Australian affiliate/company – The same principles apply for international broadcasts/webinars as for those initiated locally. Companies should ensure that the content is appropriate for an Australian audience and any discussion of products is

consistent with local approved indications and Product Information. If the content is promotional, all mandatory requirements should be communicated to the audience. For example, text embedded around the viewing frame, a holding slide at the beginning and/or end of the webinar presentation, or including the information in an email providing the link to the webinar.

Section 2.4.2 Social Media

The current provisions of the Code of Conduct pertaining to promotion to healthcare professionals (Section 2) and promotion to the general public (Section 12.3) apply to social media.

Since the rise of social media, companies have experienced heightened interest and awareness of their responsibilities in these media regarding the prohibition of promotion of prescription products to the general public and adverse event reporting. Member companies providing information via social media platforms should apply the principles of Section 2.4 of the Code. Engagement with healthcare professionals through social media and the internet must not bring discredit upon, or reduce confidence in the pharmaceutical industry.

There are two broad social media scenarios:

- company initiated and controlled activities; and
- sponsorship of a third party (such as a health consumer organisation) to develop a social media portal.

Companies have full responsibility for their own initiatives. Through their contracts with third parties, the responsibilities of each party should be described.

Companies who engage in social media activities that include discussion boards and sharing of audio and visual content should consider:

- whether discussion boards need to be monitored and how regularly;
- how to manage inappropriate conversation;
- establishing rules for participants joining a discussion forum that:
    - outline what is inappropriate conversation (e.g. offensive language, racist comments, promotion of a product) and that conversations may be monitored;
    - describes whether any content would be excluded, and the process for excluding it;
    - discussion boards may be shut down at any time;
- responsibilities for reporting of monitoring and reporting of Adverse Events reported via this media,

Information placed by Australian pharmaceutical companies on social media such as 'YouTube', 'Facebook', 'Twitter' or blogs must be aware that the company will be held liable for user generated content as evidenced by two cases in Australia:

- Facebook may be considered to be a 'marketing tool' when used by an advertiser according to the Advertising Standards Board (ASB). For example, there was a complaint against VB and Smirnoff Vodka's Facebook page 2012, which raised concerns around 'fan'-generated obscenities, sexism, racism, and depiction of irresponsible drinking[1]. In its commentary about this case reported in the media, the ACCC's expectation for Facebook is the removal of offensive or misleading content within 24 hours of posting.
- Any business that decides to leave public testimonials or other comments on their Facebook and Twitter pages will be held responsible if they are false, misleading or deceptive. Refer to the ACCC's summary of the Federal Court's ruling on a 2011 complaint against Allergy Pathway Pty Ltd.[2]

The above examples indicate the need for companies to moderate social media content and the removal of inappropriate material within 24 hrs.

If using social media sites such as YouTube, Facebook etc to make educational materials available to consumers, companies should give consideration to any potential associated content, links or advertisements irrespective of whether the company can control them, for example if displaying a video in YouTube, the company should consider

[1] http://www.kwm.com/en/au/knowledge/insights/social-media-marketing-managing-your-online-presence-in-the-wake-of-recent-asb-decisions-20130401
[2] http://www.accc.gov.au/media-release/firm-fined-for-testimonials-by-facebook-fans-and-tweeters

the “suggested clips” which may be associated with the video through similar tags. Refer to complaint 1085 in the Report of activities directed at the general public, July 2012 on the Medicines Australia website.

Any electronic forms of promotion using Social Media must be considered in context. That is, is the information medical education or promotion? If the material is promotional it must include the PBS listing information within the body of the advertisement and a reference to review the Product Information before prescribing. The Minimum Product Information may be included within the body of the advertisement and/or a direct hyperlink to the Product Information must be included. When linking to a PDF of the Product Information or Consumer Medicine Information on a third party site where the viewer cannot navigate away from the page displaying the PI or CMI, a pop-up box warning the reader they are leaving the company controlled site is not required.

See also guidance in Sections 13.6, 13.7, 13.9 and 13.10 of these Guidelines.

FIGURE 12: ENEWSLETTER ADVERTISEMENT

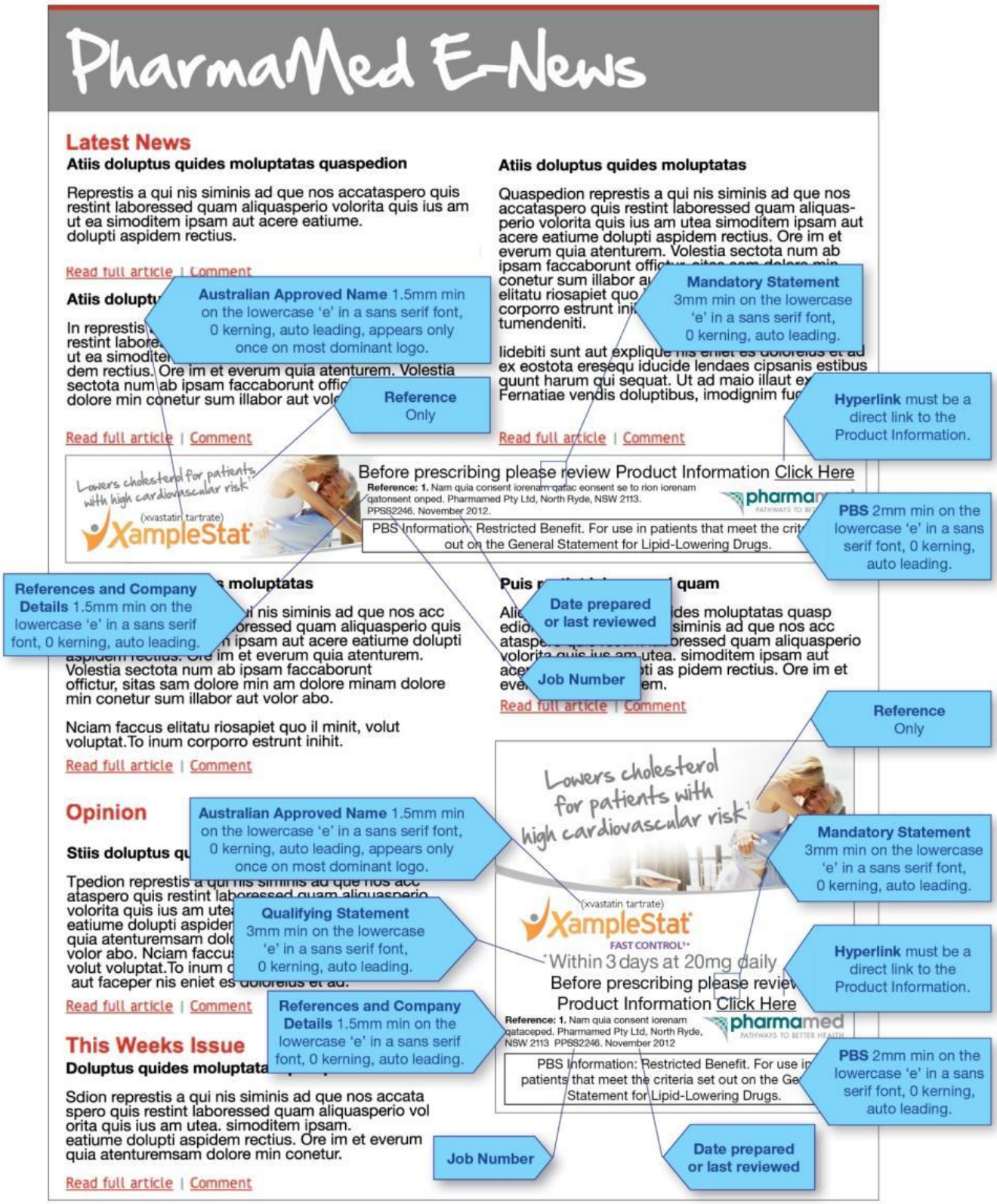


FIGURE 13A: OPENING SCREEN FOR E-DETAIL AID/SMART PHONE APP FIGURE

13B: ADVERTISING SCREEN WITH PROMOTIONAL CLAIM AND REFERENCE SMART PHONE APP

FIGURE 13C: LOCATION OF PRODUCT INFORMATION AND PBS INFORMATION IN E-DETAIL AID/SMART PHONE APP

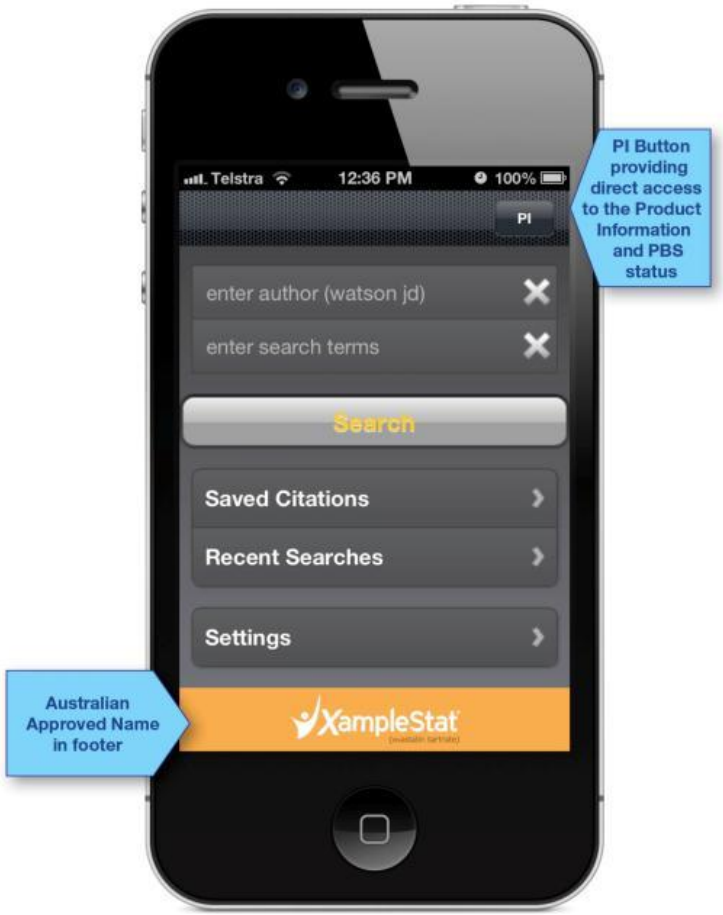


FIGURE 13D: LOCATION OF PRODUCT INFORMATION AND PBS INFORMATION IN E-DETAIL AID/SMART PHONE APP

FIGURE 14A: OPENING SCREEN FOR E-DETAIL AID/TABLET DEVICE APP

FIGURE 14B: ADVERTISING SCREEN SHOWING LOCATION OF PI BUTTON/TABLET DEVICE APP

FIGURE 14C: LOCATION OF PRODUCT INFORMATION AND PBS INFORMATION IN E-DETAIL AID/TABLET DEVICE APP

Section 2.5 Prescribing Software

The Therapeutic Goods Act and Regulations prohibit the advertising of prescription medicines to the general public. This principle is recognised in the Code.

Companies should consider the following when developing information for inclusion in a prescribing software package.

Medical Education for healthcare professionals

Any item of medical education for a healthcare professional must be included in a section of the electronic software package that would not be visible to a patient. All items must comply with the relevant provisions of Sections 1 and 2 of the Code.

Educational Information to the General Public

These items can be downloadable and used by the healthcare professional in consultation with a patient. This general information must not be product branded. Information must comply with the provisions of Section 13.6 of the Code. The item can also be provided to the patient to take away from the consulting room.

Once the doctor has electronically prescribed a specific prescription medicine, a pop up screen to support the quality use of medicines may appear, the purpose of which is to educate patients.

Patient Aids

These items can be downloadable and used by the healthcare professional in consultation with a patient once a decision to prescribe has been made. The item can also be provided to the patient to take away from the consulting room. Materials must comply with the provisions of Section 13.7 of the Code.

A company could include a pop-up dialogue box which reminds the healthcare professional to advise the patient that the packaging for the patient's medicine has changed. This could be the colour of the packaging, colour on the device (for example a pre-filled insulin device) or the size, shape or colour of the tablet.

Patient Support Programs

A company may include notification to a healthcare professional that a patient support program is available once the doctor has electronically prescribed a specific medicine. For example a pop up box which states "Do you wish to enrol this patient in the patient support program?" or "Patient Support Program materials are available to be downloaded" would be acceptable. Programs and materials must comply with the provisions of Section 17 of the Code.

It would not be acceptable for a company to include a pop up box in the prescribing software package which seeks to influence a healthcare professional's decision at the point of prescribing such as a generic, biosimilar, different class or combination product.

Section 2.6 Brand Name Reminders and items for medical education

During the review of the Code of Conduct in 2011-2012, which developed Code Edition 17, the Code Review Panel considered the provision of items on which the brand name is included for the sole purpose of increasing the awareness of the brand name (brand name reminders) to healthcare professionals. Consistent with international changes to industry codes and recommendations included in submissions to the review process, the Code Review Panel recommended that providing brand name reminders should no longer be permitted. Accordingly, Section 2.6 prohibits the provision of items formerly known as brand name reminders.

The items previously permitted to be supplied to healthcare professionals as brand name reminders, such as tongue depressors, blood pressure cuffs, examination bed covers and disinfectant hand wash are no longer allowable. Any gift or offers given to healthcare professionals must be consistent with Section 9.12; therefore simply removing the brand name from these items does not make it acceptable gift. See Section 9.12 Gifts and Offers in these Guidelines for further guidance on appropriate gifts and offers for healthcare professionals. Refilling a branded container with medical consumables, such as medical grade hand cleanser would not be permissible.

The brand name for a prescription product, with accompanying Australian Approved Name, may be included in or on materials when allowable or required. When not accompanied by a promotional claim, the requirements of Section 1 and Section 2 do not apply.

Examples of where a brand name may be included are invitations, Apps, URLs, Product Information (PI), Consumer Medicine Information (CMI), and web pages containing PIs and CMIs.

Additionally, brand names may be included on the external view of mailings, provided that there is no accompanying promotional claim, and on patient aids that will be used by the patient inside their home.

Items of medical education may be provided to healthcare professions. Items of medical education must comply with Section 4.1 and include the company name and locality.

There may be circumstances where it is not possible to include the company name and locality on the item of medical education, for example a text book. The text book may include a 'With Compliments' slip which includes the company name and locality.

An anatomical model is considered to be an item of medical education, and therefore may be provided to healthcare professionals.

Medicines Australia considers that calendars/year planners; desk sets; diaries and medical telephone message books are permitted to be provided to healthcare professionals provided they contain significant educational information for the purpose of promoting medical education or assisting with clinical practice. Guidance on advertisements used within these items, the PBS and the Product Information requirements can be found in Section 2.1.2 of these Guidelines.

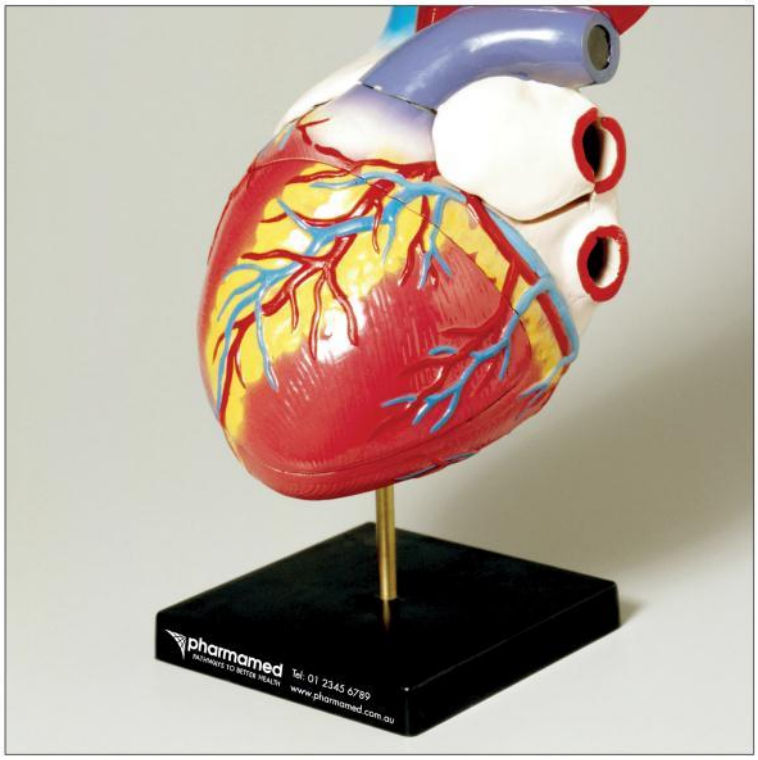
Medicines Australia is frequently asked questions about the acceptability of using a USB memory stick, flash drive or thumb drive for the provision of medical education materials. The Guidelines Working Group determined that using a USB to provide medical education must be legitimate education. For example, providing a Product Information on a USB would be difficult to justify, whereas presentations, articles, or other educational information may be legitimately issued in this form. The exterior surface of the USB may only include company branding and be able to satisfy the requirements in Section 4.1 of the Code.

USBs may also be used to provide access to educational websites (via web key for example) or to allow a healthcare professional to load clinical tools such as “health status” calculators or other instruments onto their computers.

It is acceptable to provide a healthcare professional with a Smartphone App, whether developed by the company or by a third party, as long as the App contains sufficient medical education. Guidance on advertisements used within these items, the PBS and the Product Information requirements can be found in Section 2.4.1 of these Guidelines.

For information on company branded items please refer to Table 8 and Sections 9.4.9 and 9.5.9 of these Guidelines.

FIGURE 15: COMPANY BRANDED ITEM OF MEDICAL EDUCATION (CONSISTENT WITH SECTION 4.1)



An anotomical model must include the company name and contact details

Section 2.7 Competitions

Competitions and quizzes may be run by member companies and are acceptable, but no prize or “gift” may be offered under any circumstances. Companies should ensure that requests for market research information, starter packs or products prescribed are separate and distinguishable from company run competitions.

Sponsorship of educational events at which third parties or conference organisers run competitions with prizes are acceptable, where the sponsorship is provided to support the educational content/activity. Examples of such activities would include, but are not limited to;

- “passport” activities that take place in trade display areas during an international or national congress;
- competitions published in medical/scientific journals where member company advertising may appear; and
- member company financial contributions to poster competitions held and judged by medical/scientific societies.

Companies should ensure that sponsorship funding is allocated for educational content or facilitation of such at smaller events, especially where the company is a sole sponsor. Sponsoring companies are ultimately responsible for ensuring that their financial contributions do not contribute to unacceptable components such as competition prizes or “gifts”.

Section 2.8 Communication with healthcare professional media

Section 2.8 deals with communication to healthcare professionals via media outlets that specifically target these audiences. It acknowledges that different media outlets have different audiences, so the needs of the specific target audience should govern compliance with the code. While journalists for healthcare professional media may not be healthcare professionals themselves, they are reporting solely for healthcare professionals. Therefore, materials developed for healthcare professional media should be assessed in the context of how they will be received by healthcare professionals.

These include, but are not limited to:

- Australian Doctor
- Medical Observer
- Medicine Today
- Australian Pharmacist
- Retail Pharmacy
- Australian Nursing Journal
- Australian Family Physician
- Australian Medicine
- 6 Minutes

There are approximately 80 niche titles that serve various subsets of healthcare professionals.

Healthcare professional media outlets should not be confused with consumer media outlets. Communication via consumer media is addressed in Sections 13.3, 13.4 and 13.5 of the Code.

The same principles that apply to the relationship with healthcare professionals should apply to interactions with medical media. In other words, companies may interact with healthcare professional media as they would a healthcare professional. As such, educational and promotional materials should be guided by the overall principles in Sections 1, 2 and 4 of the Code.

The examples of when it would be appropriate to issue a media release to the healthcare professional media provided in Section 2.8.1 of the Code is not an exhaustive list.

Any materials accompanying a medical media release must comply with the Code. These may include, but are not limited to: product fact sheets, therapy area fact sheets or backgrounders, and product summaries.

Medical media releases are not written as a final published story, but any company providing information to a journalist must make the assumption that the journalist may publish their media release as it stands, without further inquiry or scrutiny.

From time to time, a company may decide to host a medical media briefing to accompany the distribution of a media release. A media briefing is where journalists are invited to a closed conference or discussion session to focus on the content of the media release. The content may be delivered by a company representative or an external expert. This activity may be undertaken to provide a deeper understanding of the points raised in a media release, a clinical context and perspective, and may be best managed via a two-way dialogue with a suitably qualified expert.

While not specifically covered in Section 2.8.1, the concept of media briefings is raised here as a legitimate and useful addition to the distribution of a media release. These briefings should be educational in nature with the intention of providing information to healthcare professionals via specialised media outlets. It is worth considering Sections 9.3 and 9.4 (covering educational events) when planning and implementing a healthcare professional media briefing.

If a company engages an external expert (for example a healthcare professional), it is expected that arrangements with that expert are consistent with Sections 1.4 and 9.8 of the Code (Unapproved Products and Indications and Consulting arrangements with healthcare professionals). The Guidelines Working Group recommended that companies consider including a short statement on a media statement that outlines the relationship between the company and a healthcare professional spokesperson. It suggested the following wording could be used for such disclosure:

"Dr. X has served on advisory boards and been involved in clinical trials sponsored by [Company Name] for which compensation was received. In relation to this [Company Name] media announcement, no compensation was provided to Dr X, and the opinions expressed are their own. Dr X has been briefed by [Company Name] on the approved use of this product."

Section 2.8.3 Sponsorship of Medical Journalists to attend medical conferences

As noted in this section, guidelines which govern relationships with healthcare professionals also govern interactions with a journalist representing healthcare professional media. Therefore, the provisions of Section 9.7 of the Code (Sponsorship of healthcare professionals to attend educational events) apply when sponsoring a healthcare professional journalist to attend a medical conference.

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

Section 3 requires that certain printed advertising and promotional material for healthcare professionals, described in Section 2, must include the Minimum Product Information.

The overall purpose of the Minimum Product Information is to provide sufficient, relevant information to a healthcare professional in the context of viewing promotional material and advertisements. Healthcare professionals should have access to clinically relevant information when they are prescribing a product. The Minimum Product Information is a succinct précis of the Product Information. It is not intended to replace the full Product Information, which all prescribers and other healthcare professionals should be familiar with, or familiarise themselves with, before prescribing, recommending or administering a prescription product.

Wherever the Minimum Product Information is required to be included in advertisements or promotional material, the full Product Information must also be accessible to a healthcare professional via the Internet or telephone requests to a company's medical information department.

Section 3.2 Minimum Product Information

Section 3.2 describes the scope of information that must be included in the Minimum Product Information. It is up to a company to determine the level of detail to be included in the Minimum Product Information in relation to the contraindications, precautions, interactions and adverse effects. It should provide a fair and balanced summary of the risks and benefits of the product.

Additional content may be included at the company's discretion (eg post-marketing adverse effects).

Companies may develop Minimum Product Information documents for products that have several indications where the Minimum Product Information includes only the information relevant to a particular indication. However, any boxed warning for a product must appear in all versions of the Minimum Product Information irrespective of whether the boxed warning relates to a particular indication.

Section 3.3 Changes of Clinical significance and the addition of a Boxed Warning

A change of clinical significance is defined in the Code Glossary.

It is for a company to determine whether a change to the Product Information is 'clinically significant', taking into account this definition. Companies may choose to communicate any change in the Product Information to healthcare professionals.

Edition 18 of Code no longer specifies mechanisms by which a company should communicate a change of clinical significance to healthcare professionals. It is for a company to determine the most appropriate method to communicate a change of clinical significance.

Edition 18 of the Code emphasises that if the TGA directs a company to communicate a change of clinical significance, companies must do so.

Section 4 Educational Material directed at Healthcare Professionals

Section 4.1 Medical Education and Section 4.2 Medical Literature/Reprints

These sections cover all forms of media used to disseminate this information.

When using and referencing publications in promotional materials, companies should be aware of the particular publication's policy of use, and whether prior approval for use is required. For example, Therapeutic Guidelines Limited provides *Conditions for the Use of Therapeutic Guidelines Publications in Pharmaceutical Industry Promotion.* This policy may be found at http://www.tg.org.au/uploads/PDFs/Pharmaceutical_Industry_policy.PDF.

Electronic format of medical literature

Electronic presentation of independently produced medical literature/clinical papers through an iPad/tablet eDetail Aid must be consistent with the same guidance for printed forms as outlined in Section 4.2 of the Code.

The general interpretation and conclusions of any electronic presentation of medical literature/clinical papers 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.

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 electronic article should be specifically highlighted or annotated to draw the attention of the healthcare professional.

The electronic presentation of medical literature must contain the complete content of the presented clinical paper. It should be balanced and no part of the presented clinical paper should be omitted. The electronic article cannot be altered in any way. For ease of navigation it may include search or hyperlink functionality. For ease of interpretation it may incorporate "zoom in" functionality.

For further guidance refer to Section 2.2 Electronic and Audiovisual Media including electronic Detail Aids in these Guidelines.

Use of conference materials

Healthcare professionals may be given the full compilation of independent conference abstracts, posters, audio-visual recordings etc from a third party meeting, even if those items contain information about products with unapproved indications or not approved in Australia. This is accepted as being equivalent to educational material prepared by a third party.

A company cannot prepare and proactively disseminate (unsolicited) to healthcare professionals a compilation of a selection of posters and abstracts from a conference which includes items about unapproved products or indications relevant to their company or a competitor's products. Companies can provide such a selection where each abstract or poster or other item relates to approved products or indications.

The same principles described above apply to dissemination of information from independent conferences at company-initiated meetings.

For large multidisciplinary meetings, this requirement to provide the full compilation may be limited to the abstracts or posters in particular disease/conditions, therapeutic areas and/or drug classes on the condition that:

- the abstracts/posters provide a balanced representation of the data presented in that area at the meetings
- the material includes abstracts/posters for all products presented in this area (for example, it does not single out products unique to one company).

Reporting on Clinical Trials and Pipeline Development

(see also Section 9.6 - Trade displays and Section 13.4 Product Specific Media releases)

Any communication about products or indications still under development (or not yet approved in Australia) must not breach the Therapeutic Goods Act. This prohibits a company from promoting an unapproved product or indication to healthcare professionals or consumers.

A question often arises about whether a company can present clinical trial results for an unapproved product to healthcare professionals. It would generally be difficult to present late stage clinical trial results for a particular product in a non-promotional manner. A factual presentation on the company pipeline may be provided to healthcare professionals. Medical department personnel could provide a presentation to healthcare professionals giving an overview of products/indications in development without making any claims in relation to the results of trials. The information on a clinical trial should be provided as a factual statement of the study design, number of patients, location of trial centres, primary purpose and progress to date as long as this is communicated in a non-promotional manner.

A company could also provide non-promotional advice to a healthcare professional/s about particular clinical trials that are open for recruitment.

Refer also to Section 1.4 of these Guidelines.

Section 5 Company Representatives – Roles and Ethical Conduct

One aspect of complying with this section of the Code is that company representatives need to be aware of their environment when discussing prescription medicines.

Section 5.3 State Departments of Health, Hospital policies and operating theatre procedures

In addition to the requirements of the Code of Conduct, companies should ensure that all company representatives are aware of other protocols that may relate to their interactions with healthcare professionals. Some examples of other protocols relevant to the activities of company representatives include:

- NSW Therapeutic Advisory Group (NSW TAG)
  http://www.ciap.health.nsw.gov.au/nswtag/
- This site also includes a hyperlink to resources from the Council of Australian Therapeutic Advisory Groups (CATAG). http://www.catag.org.au/
- Victorian Therapeutic Advisory Group (VicTAG)
  http://www.victag.org.au/
- South Australian Medicines Advisory Committee (SAMAC)
  http://www.sahealth.sa.gov.au/SAMAC
- South Australian Health Department Directive on Interaction between SA Health and the Therapeutic Goods Industry
  http://www.sahealth.sa.gov.au/wps/wcm/connect/f11934004ac1fdc988f9ad1be4847105/InteractionBetweenSAHealthTGA-PHCS-PSS-1204.pdf?MOD=AJPERES&CACHEID=f11934004ac1fdc988f9ad1be4847105
- Western Australia Therapeutic Advisory Group (WA TAG)
  http://www.watag.org.au/home/
- WA Health Staff Air Travel Policy
  http://www.health.wa.gov.au/circularsnew/pdfs/13187.pdf
- WA Health Acceptance of Gifts Policy
  http://www.health.wa.gov.au/circularsnew/circular.cfm?Circ_ID=13157
- Queensland Health Medicines Advisory Committee
  https://www.health.qld.gov.au/publications/clinical-practice/guidelines-procedures/medicines/guide-pharmaceutical-reps.pdf
- ACORN Standards S24 Visitors to the Perioperative Environment Standard Statements 5 and 6 refer to Medical Company and commercial representatives
  Standard S24 is available for order from http://www.acorn.org.au/standards/shop/
- Australian Society of Anaesthetists position statement Guidelines for Visitors to the Operating Environment
  http://www.asa.org.au/UploadedDocuments/ASA%20Position%20Statement/ASA%20Position%20Statement%208%20-%20Guidelines%20for%20Visitors%20to%20the%20Operating%20Environment%20Sept%2013.pdf

Company representatives need to be aware of how these policies are interpreted and implemented within a particular institution, as well as any other institutional policies that apply to the activities of pharmaceutical company representatives.

Companies should also ensure that in any interaction with a healthcare professional where a patient may be present, such as a hospital ward or operating theatre, they act in compliance with all hospital policies including patient confidentiality arrangements. This includes company training programs in hospitals or clinics and preceptorships.

In any interaction with a healthcare professional the company representative should ensure that they do not cause inconvenience through the manner in which they make appointments with the healthcare professional, or by the frequency, timing and duration of appointment, together with the manner in which they are made, are such as not to cause inconvenience to the healthcare professional. The wishes of an individual healthcare professional or the arrangements in force at any particular practice must be observed by company representatives.

Section 5.5 Appointments with healthcare professionals

It would not be appropriate for a company representative to discuss a product, for example, in the waiting room of a surgery when this information could be overheard by members of the general public. Company representatives are encouraged to provide this information in a private environment which facilitates direct communication with the healthcare professional.

Section 5.9 Access to healthcare professionals

Section 5.9 of the Code of Conduct states “Under no circumstances shall a representative pay a fee in cash or in kind, in order to gain access to a healthcare professional.”

In 2000 the Australian Competition and Consumer Commission (ACCC) provided advice to the Australian Pharmaceutical Manufacturers Association (APMA, Medicines Australia’s former name) that it may be a breach of the Trade Practices Act (now called the Competition and Consumer Act) to preclude members from dealing with organisations that operate medical appointment making systems. While not agreeing with this view, the APMA issued a statement in February 2000 to the effect “Members should in no way feel constrained by the provisions of the Code of Conduct from entering into arrangements with third parties in relation to proposals for medical representatives or companies to access general practitioners.”

Section 6 Company Representatives – Education

The Continuing Education Program

The Continuing Education Program contains six core programs, designed to guide medical representatives through the information, knowledge and skills required in the performance of their professional duties.

The core programs are:

- **The Medicines Australia Code of Conduct** – ethical practices within the pharmaceutical industry, including the obligations and practices of companies in their relationship with the health care industry and the public;
- **The Pharmaceutical and Healthcare Industry** – the historic development of the industry, government regulatory processes and the industry's role in the Australian health care system;
- **Human Anatomy and Physiology** – introductory anatomy, physiology, cellular life, tissues, defence mechanisms, and an overview of nine body systems. This program is a pre-requisite for 'Introduction to Pharmacology'.
- **An Introduction to Pharmacology** – pharmacokinetics and pharmacodynamics, how drugs are administered, transported through the body and absorbed;
- **Understanding Product Information** – an overview of the scientific, medical and therapeutic information contained in Product Information, including how the information is structured to comply with Therapeutic Goods Administration requirements; and
- **Understanding Clinical Evidence** – a systematic approach to the analysis of published clinical papers, including how clinical trials are designed and conducted, and the four phases of clinical trials.

Timeframe

All medical representatives (see Section 6.4 and the Glossary definition of 'medical representatives') must commence the Continuing Education Program within six months of commencing work in the industry. All six programs must be completed within two years of enrolment in the course.

Extensions

No extensions will be granted. The Code is explicit (Section 6.4) that the full program must be completed within two years. See also below regarding contracted and part-time employees.

Parental or Extended Leave

Companies need to demonstrate that employees who take parental or extended personal leave during studying are moving through the course at an equivalent rate as ongoing full-time employees. Companies are encouraged to develop a study plan for employees to recommence their studies when they return to the workforce.

Recognition of prior learning (RPL)

Students who have an eligible qualification may apply for recognition of prior learning for Program 3 - Human Anatomy and Physiology, Program 4 – Introduction to Pharmacology and Program 6 – Understanding Clinical Evidence. Eligibility for RPL will be at the discretion of the course provider.

Contracted and part-time employees

Medical representatives who are employed on a contractual basis must also complete the CEP. Companies should be able to demonstrate that contracted and part-time employees are moving through the course at an equivalent rate as full-time employees. Section 6.5 allows that medical representatives that are contracted for less than two years must complete the full program in the equivalent of two years of permanent employment.

Is the Code of Conduct Update mandatory?

No, the Update Course is not mandatory. Once a student has completed their required courses (CEP Programs 1-6) they are considered to have complied with Section 6 of the Code. The Update Course is developed every time the Code of Conduct is reviewed. This course is made available online in the same manner as all of the other courses. It provides an in-depth look at the changes made during the review and how this will impact on the development of materials as well as how sales representatives interact with healthcare professionals. This course is offered at a lower cost than the other modules provided, and does not take as long to complete. It is strongly recommended that the Update Course is completed to ensure all staff are adequately briefed on the changes made to the code.

Do medical representatives have to start the CEP with Program 1?

The Code does not require that students must start with Program 1; however it would be the most suitable place to start. This program sets the platform for interactions with healthcare professionals. Medicines Australia strongly suggests that students start with Program 1, and then they complete the remaining programs in any order they wish (with the provision that Program 3 is completed before Program 4).

Section 6.5 Requirement to complete Program 1 Code of Conduct of the Continuing Education Program

The requirement for company representatives who are directly involved with the development, review and approval of promotional material to complete the Code of Conduct component of the endorsed Medicines Australia education program only applies to company employees or agents (including agents working under a contract to the company but not directly employed by the company). It does not apply to third party contractors such as advertising agencies, although these personnel are encouraged to also undertake the Code of Conduct component of the endorsed Medicines Australia education program.

This requirement does not include managing directors, clinical research associates, medical information, corporate affairs personnel unless these personnel are also responsible for the development, review and approval of promotional material and patient education material. However, all company personnel should be aware that the Code of Conduct applies to all company interactions with healthcare professionals.

Any person newly employed in a role (whether a new employee or transferred from another position) where their primary employment is the development, review and approval of promotional materials for prescription medicines or the review of promotional materials must have completed the Code of Conduct component of the endorsed Medicines Australia education program within 12 months of commencing employment.

If a person previously in this role (development, review and approval of materials) transfers to a new company there is no requirement to complete the Code of Conduct component of the currently endorsed Medicines Australia education program again. However if the company representative was not employed in this role previously they must complete the Code of Conduct component of the endorsed Medicines Australia education program within 12 months of commencing employment in this role.

It remains at the company's discretion to go beyond the requirements of the Code, for example by requiring all staff to complete the Code of Conduct component of the currently endorsed Medicines Australia education program, rather than only those required to do so under the Code.

Pharmaceutical companies are encouraged to ensure that medical representatives and relevant staff are aware of amendments to each edition of the Code of Conduct by completing the Code Refresher Module or by providing internal company training.

Section 6.6 Australian Privacy & Competition and Consumer Legislation

The intention of Section 6.6 is that all company representatives must regularly undertake training in the Australian Privacy and Competition and Consumer legislation if they are directly involved with the development, review and approval of promotional material for healthcare professionals. Company representatives producing educational material for use by consumers and representatives directly promoting the company's products to healthcare professionals must also undertake this training.

Section 7 Starter Packs

In 2003 the Galbally Review recommended that all State and Territory regulations be repealed and a national set of provisions be incorporated into the Medicines Australia Code of Conduct. The Section 7 provisions were developed in consultation with the National Coordinating Committee for Therapeutic Goods (NCCTG) and other stakeholders.

Section 7.3 of the Code describes appropriate reasons for the supply of Starter Packs, which are not limited to a healthcare professional becoming familiar or gaining experience with a product. It is the responsibility of the company to ensure that a HCP is aware of their obligations when providing starter packs to patients.

In most instances, the Code requires that a starter pack should not exceed 1/3 of the PBS primary quantity for a product. Examples of where it may be acceptable to provide a trade pack instead of a starter pack can be found in Section 7.4 of the Code.

Companies and representatives should be aware of the current state sampling regulations and the provisions of the Code. The current State Sampling Regulations can be accessed at:

http://medicinesaustralia.com.au/code-of-conduct/continuing-education-program-cep

All companies should ensure that representatives supplying Starter Packs understand these provisions and develop and maintain appropriate recording systems so that compliance by authorised representatives (including "third party" agents) can be demonstrated.

Starter Packs should only be supplied to healthcare professionals appropriate to their legal authority to prescribe and dispense such products. For example, it would not be appropriate to supply to a nurse practitioner starter packs for medicines that they are not permitted to prescribe.

In addition, companies should be aware of additional policies regarding the supply of starter packs in hospitals and other institutions.

In 2012 the Council of Australian Therapeutic Advisory Groups developed Guiding Principles for Managing Use of Medication Samples in Australian Public Hospitals. These principles outline the need for all starter packs to be received and managed through hospital pharmacy units in Australian Public hospitals. These principles can be retrieved from http://www.catag.org.au/wp-content/uploads/2013/02/CATAG-Guiding-Principles-Samples-Nov-2012.pdf

Similar requirements are found at the individual State Health Department level, as follows:

South Australia

Policy Directive Samples (Product Starter Packs) Policy developed by: South Australian Medicines Advisory Committee, PH&CS Approved at Portfolio Executive on: 15 December 2011, retrieved from

https://www.sahealth.sa.gov.au/wps/wcm/connect/24e25d804aef93c9b9b2bfe3156d3a20/Samples-PHCS-1204.pdf?MOD=AJPERES&CACHEID=24e25d804aef93c9b9b2bfe3156d3a20

Western Australia

Guidance Document for Western Australian Public Hospitals and Health Services and their Staff on Liaison with the Pharmaceutical Industry, September 2010
http://www.watag.org.au/watag/docs/Guidance_Liaison_Pharmaceutical_Industry.pdf

Victoria

Details of the requirements for the Supply of Product Starter Packs by Wholesalers in Victoria is available on the Victorian Drugs and Poisons website http://www.health.vic.gov.au/dpcs/control.htm

Labelling

Where possible there should be sufficient space on the primary label (i.e. the primary packaging label) for a dispensing label to be applied. In relation to the labelling of starter packs, Section 7.8 states that companies should either supply adhesive labels pre-printed with fields for the prescriber to complete or pre-print these fields on the primary packaging.

Such labels should comply with Appendix L of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). Some elements of Appendix L will already appear on the primary label. The relevant fields are:

(a) the name and contact details of the dispenser supplying the substance;

(b) adequate directions for use;

(c) the words “KEEP OUT OF REACH OF CHILDREN” in red on a white background;

(d) if the substance is intended for external use only, the word “POISON”, or the words “FOR EXTERNAL USE ONLY”, in red on a white background;

(e) the name of the person for whom it was dispensed.

If the whole contents of a starter pack will be administered to a patient by the healthcare professional rather than dispensed to the patient to take home and self-administer, a company would not need to supply pre-printed adhesive dispensing labels or pre-print the fields on the primary packaging.

It must be clear to a HCP that when providing starter packs to patients, clear instructions should be included on the starter pack.

If the starter packs are included within another container, for example as part of a starter kit which includes the Consumer Medicine Information and/or patient education material, a company must consider the provisions of Sections 13.7 and 17 of the Code. A company must also consider whether there are any labelling obligations when including the starter packs in another container.

Requirement for signature when requesting or receiving starter packs

The intention of this provision is to ensure that a healthcare professional actually requests the starter packs and that when starter packs are supplied there is a record kept of the supply to ensure the security of the starter packs.

A healthcare professional must give their signature either when requesting or receiving starter packs, in order to receive them. This is intended to allow for emailed requests for starter packs. If an email request is received, the healthcare professional’s signature must be obtained upon delivery of the starter packs.

Where electronic requests for starter packs are received by a company or agent acting on behalf of a company, either an electronic or hard copy of the request and the record of the supply must be retained.

Number of Starter Packs

The Code does not stipulate a maximum number of starter packs that can be provided to healthcare professionals but does refer to the needs of those healthcare professionals when determining how many starter packs can be provided. It is the responsibility of the Company to ensure that the number of starter packs ordered by the healthcare professional reflects the needs of that healthcare professional for reasons listed under Section 7.3 of the Code until the representative’s next visit.

In the past the Code Committee has considered complaints where a number of starter packs were packaged together and provided to healthcare professionals for use by their patients. This practice caused some concerns within the Committee as it was seen as a means of circumventing both the size and quantity requirements of the Code. Where a starter pack of one third the trade pack size would only take a patient midway through the necessary titration period as required in the approved Product Information, the Committee has expressed the view that if it was in the best interest of patients this could justify the provision of sufficient tablets in the starter kit to achieve a quality use of medicine outcome.

Where there is a clinical rationale for bundling starter packs and the starter packs are placed together in a clear or transparent outer wrapper for the convenience of the patient, this would be acceptable as the contents and labelling could be seen through the wrapper. However, if the starter packs were included in an opaque container which was intended to be given to the patient by the prescriber, the outer wrapper/container would need to comply with the Labelling Order. Alternatively, the prescriber would need to be instructed to remove the starter packs from the outer packaging before providing them to the patient.

If a company undertakes this bundling of starter packs it must be in a situation to prove to the satisfaction of the Committee that this practice was not an attempt to circumvent the requirements of the Code was undertaken in the best interests of the patients, supported the quality use of medicines and complied with the provisions of the Code.

In considering a complaint and subsequent appeal (Complaint 854 in the Code of Conduct Annual Report 2007) the Code and Appeals Committees were of the view that there is no justification for providing trade packs in place of several starter packs. For a presentation pack where each tablet in the pack has the same ingredients and is the same strength, a starter pack and not a trade pack must be used. However, for a medicine in a calendar pack, where the tablets must be taken sequentially and not all tablets in the pack have the same active ingredients there may be justification for supplying more than the third-size starter pack.

Provision of Consumer Medicine Information (CMI)

To ensure that patients have access to the CMI, companies should ensure that the CMI is either included in the starter pack or supplied in a manner that will enable the doctor or hospital pharmacist to give the CMI to the patient at the same time the starter pack is provided. It is not acceptable to simply refer the patient to the company website as not all consumers have access to the internet.

Section 8 Product Familiarisation Programs (PFPs)

Company representatives must be aware of State and individual institutional requirements for Product Familiarisation Programs in specific hospitals, particularly the requirements for management and distribution of the product within the institution. For example, the South Australia Health Department has issued the Policy: Medicines Access Programs (Product Familiarisation Programs and Expanded Access Programs), 15 December 2011

http://www.sahealth.sa.gov.au/wps/wcm/connect/83147d004ac200148921ad1be4847105/MedicinesAccessPrograms-PHCS-PSS-1204.pdf?MOD=AJPERES&CACHEID=83147d004ac200148921ad1be4847105&CACHE=NONE

The Council of Australian Therapeutic Advisory Groups (CATAG) has also issued *Guiding Principles for Medicines Access Programs in Australian Public Hospitals* (http://www.catag.org.au/resources/). These Guiding Principles refer to Product Familiarisation Programs as well as other programs and are applied in many public hospitals.

Section 8.1 of the Code requires that a company will make available the rationale for a PFP without delay, but in any event in no longer than 10 working days. This means that the rationale must be provided on request within 10 working days of receipt of a request from any person.

If a company decides to extend the period of enrolment for the PFP, the PFP must still only allow each healthcare professional to enrol a maximum of ten (10) patients in the program.

Section 8 only applies to Product Familiarisation Programs. A pharmaceutical company may sell its products at any price or even supply at no cost to the patient, provided they are supplied in accordance with legal requirements. This is outside the scope of the Code of Conduct.

If a program has the characteristics of a Product Familiarisation Program as described in Section 8 and the Glossary then it should be determined to be a Product Familiarisation Program irrespective of the objective of the company. Programs known as “Free Stock Programs” and “Early Access Programs” should not be disguised promotional activities. An example of a complaint concerning a PFP is complaint 1081 (Code of Conduct Annual Report 2012).

Section 8.4 of the Code requires that the patient information document must include a section for the patient to consent to receive the product under the PFP. This consent is to be retained by the healthcare professional.

Section 8.7 allows a company to supply trade packs for a PFP if the product is dispensed through a pharmacy or other authorised dispensary or dispenser (note that a dispenser is a healthcare professional with the rights to prescribe and dispense the medicine supplied under the PFP). If a trade pack is supplied for a PFP, companies should note that these packs should be labelled as though they are a starter pack as required by Section 7.8 of the Code or, when supplied through a pharmacy, are dispensed and labelled by the pharmacist.

Section 8.11 of the Code requires that companies must promptly accept the return of their products supplied under a PFP. This becomes particularly important if companies have supplied trade packs under a PFP. Companies should determine how any trade packs remaining with a pharmacy or other authorised dispensary or dispenser will be returned to the company. This should be included in the clinical rationale for the PFP.

Section 9 Relationship with healthcare professionals

Some provisions in Section 9, such as provision of hospitality and travel, also apply to interactions that occur when conducting clinical research (see the introductory paragraphs in Section 10 Research of the Code).

Section 9.1 General Principles

This section covers activities where companies interact with healthcare professionals about prescription medicines.

Interactions with healthcare professionals include the following activities: sales calls, educational events, consultancy arrangements, advisory boards, sponsorship of healthcare professionals, or medical practice activities sponsored by financial support.

There are many forms of interactions with healthcare professionals but as a general principle all interactions must:

- successfully withstand public and professional scrutiny
- conform to professional and community standards, and
- have the primary objective of enhancing medical knowledge and the quality use of medicines in Australia.

Medicines Australia encourages members with multiple divisions (OTC, diagnostic, and medical devices as well as prescription medicines) to consider the issue of reputation and image when codes other than that of Medicines Australia permit entertainment of healthcare professionals.

Section 9.1 notes that the maximum cost of a meal (and beverages) imposed under Section 9.4.3 applies to all situations where a meal is provided to a healthcare professional in Australia, including in association with an Advisory Board meeting, consulting arrangement or any other situation that is not an educational meeting.

Definition of 'Healthcare professional'

The definition of a 'Healthcare Professional' in the Code Glossary states:

> *A person who is registered as a health practitioner in Australia and who in the course of their professional activities may prescribe, dispense, recommend, supply or administer a prescription medicine.*

This definition encompasses those healthcare professionals to whom a company may promote a prescription medicine. It is intended to be entirely consistent with the Therapeutic Goods Act 1989 ('the Act') provisions that prohibit promotion of prescription medicines to anyone other than a healthcare professional. However, the Code does not cover all healthcare professionals as defined in the Act, such as practitioners of traditional Chinese medicine, herbalists and homeopaths.

In relation to particular groups where questions arise about the definition of healthcare professional:

- pharmacy assistants and medical practice managers are not identified as healthcare professionals in the Act (unless they are also qualified and registered healthcare professionals).
- medical and pharmacy students including medical and pharmacy interns are not healthcare professionals as defined by the Act, which refers to 'medical practitioners' and 'pharmacists'. A healthcare professional may request that a student in their charge who is studying to become a healthcare professional participate in a company interaction involving product promotion. The healthcare professional must remain present for the duration of the interaction and should be the primary recipient of any promotion.
- there are a number of healthcare professionals who, in their working capacity, might recommend a prescription medicine to a prescriber. These include dieticians and psychologists. Section 42AA of the Act specifically identifies nutritionists and psychologists as healthcare professionals to whom advertisements may be directed. A dietician would be regarded as equivalent to a nutritionist.

Additional guidance on sponsorship of healthcare professionals and healthcare professional activities

Section 9 of the Code recognises the valuable contribution the pharmaceutical industry makes to the healthcare professions through the sponsorship of various activities. The Code sets out when such sponsorship is appropriate and uses the tests outlined in Section 9.1.

These tests state that if a company wishes to sponsor a healthcare professional activity, the sponsorship must:

- be able to successfully withstand public and professional scrutiny
- conform to professional and community standards of ethics and good taste, and
- have the primary objective of enhancing medical knowledge and the quality use of medicines in Australia.

In this way the industry believes health care outcomes will be enhanced in a socially responsible manner.

Companies must ensure that there are no obligations to prescribe a product based on the sponsorship and that nothing should be offered or provided which would interfere with the independence of a healthcare professional's prescribing or dispensing practices.

Companies must ensure they have documented the way in which they provide sponsorships and the criteria they use based on the requirements of this Code. They must also be fully aware of what their sponsorship funds are buying to ensure that they can comply with the requirements set out in this section. The use of formal agreements is recommended.

Sponsorship should not be used as a vehicle to avoid other requirements of the Code. For example, a college or society should not be influenced to hold a sporting event for healthcare professionals that could be sponsored by a company and thereby avoid the requirements of Sections 9.4.6 and 9.5.8 of the Code that prohibit such events because they are a form of entertainment.

Sections 9.3 Educational Events, 9.4 Company Educational Events held in Australia and 9.5 Sponsored Educational Events

The purpose of these sections is to detail how the industry should contribute and interact in regard to educational meetings. The Code recognises that the industry plays a vital role in the provision of accurate and reliable information to healthcare professionals by a number of means, including the holding of educational meetings, the sponsorship of such meetings or the involvement in educational meetings.

Educational events are important for the dissemination of knowledge and experience to healthcare professionals. Therefore, companies are encouraged to participate in such events while ensuring the independence of speakers is maintained. The primary purpose of an educational meeting must be the enhancement of medical knowledge and the quality use of medicines.

Companies should not offer education to healthcare professionals with the objective of personal improvement or financial gain for the healthcare professional. However, provision of training that will enhance the interaction of healthcare professionals with their peers or patients may be justifiable.

Please also review the Transparency Reporting Requirements guidance provided in these Guidelines for further advice on the appropriate reporting of these events.

Section 9.4.1 Educational content at Company Educational Events

(see also Sections 1.4 – Unapproved products and indications and 4.1- Medical educational material in these Guidelines)

It is recognised that it is important to respect and maintain the independence of the speaker, but it is also important for a company who has organised an educational meeting to ensure that it meets its responsibilities under the Code. Company representatives should brief the speaker about the company's responsibilities under the Code and the scope that it would like the speaker to cover and explain that the company must not be perceived to be encouraging use of unapproved products or unapproved uses of approved products. This must be documented and must be available to the Code Committee should a complaint be lodged. A company should be able to provide, on request, evidence of a healthcare professional being adequately briefed. This may be in the form of contemporaneous file notes following a verbal briefing or a more structured briefing document which the healthcare professional signs.

A company's responsibilities for a meeting that it has organised, convened and paid for are greater than for educational meetings where the topics, content and speakers are determined wholly independently of any company involvement. Presentations distributed to healthcare professionals following an educational event may be considered a promotional item and therefore would need to comply with Sections 1, 2 and 3 of the Code.

For company initiated educational events, the educational content and speakers are described in the Code as typically being initiated and managed by the company with the educational program reviewed and approved by an internal company process. A company might decide to establish an independent scientific faculty (i.e. a Steering

Committee) to provide a more independently developed educational program and speakers. The scientific faculty could be formed from peer-recognised experts who design the scientific content and select the speakers for the event. However, the organising company remains responsible for the conduct of the meeting. The scientific faculty should be briefed by the company about the company's responsibilities under the Code. The scientific faculty should keep the company informed of the proposed program, topics and speakers.

In 2016 the Code of Conduct and Code Appeals Committees considered a complaint that concerned whether the subject company had promoted a product prior to its registration in Australia through the content of healthcare professionals' presentations given at three educational meetings (see the Code of Conduct Quarterly Report for April – June 2016). Two of the meetings were third party educational events and one was a company educational event held in conjunction with a third party educational event. The subject company was not found in breach of the Code. Key issues considered in relation to this complaint included:

- If one or more company personnel attend meetings of the independent scientific or steering committee for an event, it is important to clearly document the purpose of the sponsoring company personnel's attendance. If the company personnel are present to attend to logistical arrangements for the meeting, this should be clear. The presence of a company person at a meeting of the scientific or steering committee does not necessarily compromise the independence of that committee. However, there should be clear supporting evidence and documentation that would demonstrate that all decisions about topics, content and speakers are made independently of the sponsoring company.
- The inclusion of a company speaker in the program for an independent scientific meeting is not prohibited by the Code of Conduct, but should be an exception rather than a general rule and should only occur if endorsed by the independent steering committee for the meeting.

A company's responsibilities apply to all meetings it convenes and arranges, including where an educational presentation is repeated in a series, such as where an international speaker provides a presentation at several locations over several days. If a concern arises in relation to the content of the educational presentation during the series, it would be expected that the company representative would counsel the speaker prior to the next presentation to ensure that the company's responsibilities with respect to the Code are maintained.

Section 9.5 Sponsored (third party) Educational Events

This section covers the sponsorship of educational meetings that are organised by third parties such as a college or society, and smaller regional educational meetings that are organised by an area health service, hospital department or group of healthcare professionals.

The Code does not intend to apply the pharmaceutical industry's standards to such third party organisations, but it does require companies to ensure when they are making sponsorship decisions that will maximise the enhancement of medical knowledge, improve the quality use of medicines and conform to community standards. Requests for sponsorship of third party meetings that do not contain a suitable level/quality of medical education should be declined. This includes medical association or departmental meetings that do not have any educational component.

This section would apply, for example, if a company is invited to sponsor a conference dinner at an educational meeting. The company must ensure that it examines any hospitality or entertainment provided at that dinner and that the educational content of the meeting has merit and is the primary purpose of the meeting.

For example, a company could provide sponsorship of a conference dinner if it was not lavish, involved an educational speaker and there was incidental entertainment such as a string quartet in the background. The intention is that any entertainment included in a dinner that is sponsored by a company should not be a focal point during the dinner, such as a concert presentation, dance band etc. The test will be whether the entertainment detracts from the educational intent of the meeting in total and would be able to successfully withstand public and professional scrutiny. A useful test for companies may be whether they could support their choices if questioned by the media. This test applies to both domestic and international events.

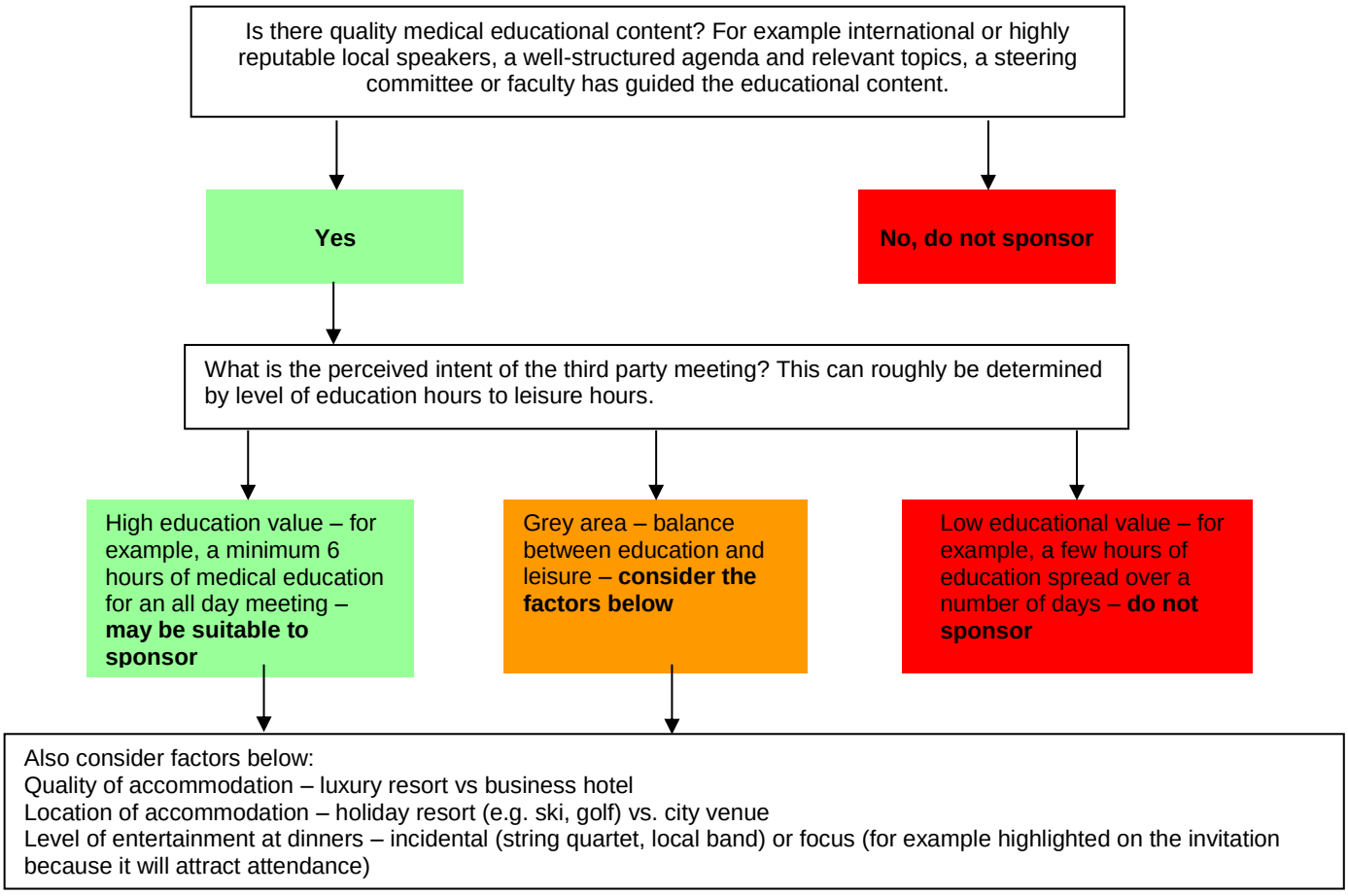
Companies are strongly encouraged to support the educational content of such meetings rather than any related hospitality. Companies should avoid making a commitment before a draft scientific agenda has been determined or sponsorship agreements or contracts are available for review.

It is recommended that companies draft their own third party agreements or add an addendum to those available from the organiser. This will ensure major changes to hospitality, entertainment, venue or educational hours are discussed and agreed with the sponsoring company.

It is advised that third parties be made aware of the Medicines Australia Code of Conduct and its intent. This will help these third parties in understanding why a sponsorship of their meeting may or may not be considered appropriate.

The following list of questions in Figure 16 may be helpful when considering whether to sponsor a third party educational event.

FIGURE 16: SPONSORSHIP OF THIRD PARTY EDUCATIONAL EVENTS



Section 9.4.2 Venue selection (Company organised Educational Events) and 9.5.4 (Sponsored Third Party Educational Events)

Company Educational Events

For educational meetings organised by companies, the venues must be chosen on the basis of their accessibility and facilities to contribute to the enhancement of medical knowledge and the quality use of medicines.

Given the professional standing of the audience to which medical information is provided, it is reasonable to use venues that reflect this audience. For example, a five-star hotel in a major city may be an appropriate venue if it had all the facilities which would enhance the imparting of medical knowledge, such as dedicated conference facilities, and could successfully withstand community scrutiny.

For meetings outside major cities, companies must choose venues that do not emphasise leisure and or sporting facilities. However, a venue that has a dedicated conference facility and can manage and supply the quality provision of education, but also has a golf course attached or located nearby may be appropriate. It would be unlikely that a regional meeting located at a golf club which provides limited conference facilities would meet the requirements of the Code.

However, some hotels which have adequate conference facilities may not be suitable choices if in the public's mind they are promoted and/or perceived as luxury resorts where the emphasis is on leisure and recreation. Companies will need to consider the choice of these venues carefully and be able to support their choice particularly in relation to community standards.

It is also important to consider the venue and its location in the context of whether the educational event is national, regional or local. Consider such things as the distance from the airport, and the cost of a city hotel compared with a suburban or country hotel.

A list of 'approved venues' for education and/or hospitality has not been created by Medicines Australia as it is each company's responsibility to determine the appropriate venue and hospitality required for the medical education to be provided.

Sponsored (third party) Educational Events

For educational meetings organised by a third party and sponsored by a company, the company should consider whether the venue is appropriate for the event.

If a medical education meeting is commonly held in the healthcare professional's institution (for example a journal club) the sponsoring company must be able to justify the choice of a venue outside of the healthcare professionals' workplace, such as a restaurant. In these circumstances the balance between education and hospitality may not be considered appropriate and the selection of the venue would need to be able to be justified.

Sections 9.4.3 & 9.5.5 Meals and Beverages/Hospitality

Any hospitality (such as meals, beverages and accommodation) must be secondary to the quality and duration of educational content provided to healthcare professionals. For further guidance please review Tables 6 - 8d in these Guidelines.

Company Educational Events

If a company is holding its own educational meeting it should ensure that any hospitality that is offered is consistent with the professional standing of the delegates but justifiable in the context of the quality and duration of the education provided. Companies should remember that hospitality must always be secondary to the educational purpose of the meeting. An appropriate level of hospitality would be what is expected at a normal business meeting.

Meals (including beverages) offered by companies to healthcare professionals within Australia must not be in excess of $120 (excluding GST and gratuities). This is a per person cost for a single meal. Companies are to ensure that provision of meals (including beverages) to healthcare professionals is not extravagant. Companies may have more stringent internal policies and limits. Hospitality must be secondary to the education provided. It is only appropriate in exceptional circumstances where there is substantial educational content provided that the maximum meal and beverage limit of $120 is reached. It is an expectation that a breakfast or lunch would be well below this limit. The Code of Conduct provides the example of a dinner at a learned society conference. This example seeks to convey that there must be high quality, substantial education provided in order to justify reaching the $120 limit. An

educational meeting with one to two hours education provided would not justify providing hospitality (meal and beverages) at a cost of $120.

It is important for companies to ensure compliance with the meals and beverage limit of $120. Should the cost of a meal (including beverages) provided to a healthcare professional exceed $120, this would constitute a breach of Edition 18 of the Code of Conduct. Companies are to ensure compliance with the $120 maximum limit through internal policies and procedures to monitor hospitality expenditure and implement remedial actions in the event of a possible breach. The Medicines Australia Monitoring Committee will review company policies and procedures to ensure compliance with Section 9.4.3 of the Code.

Sponsored (third party) Educational Events

It is acceptable to provide appropriate hospitality to delegates at a third party educational meeting held locally or overseas such as a college or society annual conference. All hospitality must be secondary to the educational purpose of the meeting. Meals should not be extravagant or exceed standards which would meet professional and community scrutiny and must not involve the provision of entertainment.

Guidance on hospitality as part of sales calls and meetings within the surgery

If during any interactions with healthcare professionals, such as a sales call or surgery meeting by a medical representative, hospitality is offered, it must be modest, secondary to the intent of the meeting and must satisfy professional, industry and community standards. Sales calls which include hospitality and occur outside the practice or healthcare professional's office should only occur when it is able to be justified. If a sales call is not able to be held in the healthcare professional's surgery or practice, it should occur in the most appropriate, private location available.

The provision of hospitality should not be offered to practice staff because the primary purpose of the interaction is to provide information regarding prescription medicines to healthcare professionals. However, should members of practice staff be provided incidentally with hospitality that has been provided for the benefit of healthcare professionals this may be appropriate in limited circumstances, but companies must not enter into any arrangement whereby access to the practice is on the basis of the provision of the hospitality.

Section 9.4.4 Travel (company organised educational events held in Australia)

The Code sets out the appropriate levels of travel that should be offered to healthcare professionals when they are being supported to attend a company-organised educational meeting.

It is permitted to pay for or subsidise the cost of travel for healthcare professionals to attend educational meetings. If the meeting is held within Australia or New Zealand, travel must be by economy class only (not premium economy). The only exemption is a documented medical condition which necessitates business class travel. Documentation can take the form of a signed letter from the sponsored healthcare professional. For international travel (other than New Zealand), either economy or business class can be used.

For both domestic and international educational events, accommodation costs may include an allowance for meals while travelling, and transfers. These allowances should reflect the professional standing of healthcare professionals, but should not be extravagant and they must be able to withstand community scrutiny.

The intent of the section regarding travel arrangements is to allow reasonable time for a healthcare professional to travel to and from an educational meeting without providing additional time for leisure or sight-seeing whilst at the location of the meeting. A company may not fund or facilitate travel to or from a location so as to allow leisure time for the healthcare professional. This includes where the healthcare professional pays for their own accommodation at the destination or flight changes.

It is acceptable for healthcare professionals to arrive at a venue in sufficient time to effectively participate in the meeting. This will vary according to the distance travelled, including travel to and from the airport. Departure to return home should be as soon as practical after the conclusion of the event. Departures should be timed to coincide with the first available flight after the end of the event. In most cases this will be on the day the event/(s) has ended. Companies must be able to justify the time allowed at a destination before and after an event with respect to available flights, the start and finish time of the meeting and total travel time.

Companies may need to consider whether it is appropriate to provide the healthcare professional's return flight if a delegate plans to attend subsequent educational events at that or other destinations independently of the company.

This would enable the sponsoring company to adhere to the main principle of travel being provided by the most practical direct route.

Companies must bear in mind the requirements of hours of education listed in section 9.4.5 of the guidelines when considering travel schedules.

Section 9.4.5 Accommodation (Company organised meetings in Australia)

It is permitted for companies to pay for or subsidise the cost of accommodation for healthcare professionals attending medical educational meetings. Companies need to carefully consider whether providing accommodation is appropriate, based on the length and type of meeting, its location and the origin of the attendees. Accommodation should generally not be provided for healthcare professionals residing in the city/town where the meeting is held. The Guidelines Working Group acknowledged that companies will need to make individual decisions as to whether it is justifiable to provide accommodation for local healthcare professionals. The principle should always be "is it justifiable for a particular healthcare professional with regard to the structure of the educational program, the distance between the venue and the person's residence, the time of day etc".

Regarding the provision of accommodation at company held medical education events the following guidance is given:

- A minimum of 6 hours of direct medical educational content (i.e. excluding lunch and other breaks) is required for healthcare professionals to justify overnight accommodation, except when the origin of the healthcare professional requires overnight accommodation due to the distance travelled and flight availability for example, travelling from a rural location or a distant state is required, two nights' accommodation may be appropriate.
- For multiple day meetings, a minimum of 9 hours of direct medical educational content (i.e. excluding lunch and other breaks) is required to justify more than one night's accommodation except when the origin of the healthcare professional requires an extra night's accommodation due to the distance travelled and flight availability

For further guidance please review Tables 6 – 8 of these Guidelines.

Sections 9.4.6 and 9.5.8 Entertainment

A primary principle in the Code is that entertainment must not be provided to healthcare professionals. This would include the provision of tickets to cultural, sporting or artistic events, the inclusion of a band as a featured attraction at a dinner meeting or an invitation to a corporate box at a sporting event.

The industry has agreed that its role is not to provide entertainment to healthcare professionals, but to be their partner in the enhancement of positive health outcomes by providing reliable and accurate information about its prescription medicines available in Australia.

See Section 9.5 of these Guidelines for guidance as to negotiating sponsorship of third party educational events where entertainment will be provided.

Sections 9.4.8 and 9.5.7 Costs incurred by partners, travelling companions or families of healthcare professionals

Any travel costs of companions or family members accompanying a healthcare professional to an educational event must be the responsibility of the healthcare professional and not be paid for or subsidised by companies. Companies should explain that airline tickets cannot be exchanged for multiple lower priced tickets that would allow a companion or family member to travel with a healthcare professional at the company's expense. If a company is reimbursing the healthcare professional for self-purchased airline tickets, the company must receive a copy of the itinerary with the invoice to ensure only the airfare of the healthcare professional is reimbursed.

Companions and family members can join healthcare professionals at educational meetings but any costs they incur must not be paid for or subsidised by the company. An estimate of the costs that are likely to be incurred by companions and family members should be advised to healthcare professionals considering taking a family member or companion to ensure they are aware of the costs that will be charged to those individuals. Companies cannot pay any costs on behalf of partners. The healthcare professional is responsible for paying all additional costs incurred by the partner, companion or family members, directly to the venue.

It is possible that additional accommodation costs will be incurred if a standard hotel room is shared by family members or companions.

Sections 9.4.9 and 9.5.9 Provision of company-branded items at educational events

These sections of the Code allow for the provision of company-branded pens and notepads to delegates attending a company organised or third party educational event. The intent of these provisions is to allow companies to provide a limited number of specific, non-promotional company branded items to be used by delegates attending the educational event. **These items can only be provided to delegates at a company educational event or a sponsored educational event that companies would report under Section 41.2.2 of the Code** (or would have reported, when educational event reporting is no longer required).

Product branded pens and notepads are no longer permitted under the Code. (See Section 2.6 of these Guidelines for guidance on the prohibition on the supply of product brand name reminders).

Company branded pens and notepads may also be provided to delegates attending an Advisory Board or clinical investigator meeting.

For the purpose of these items (pens and notepads) it is acceptable to include a company/corporate:

- name
- logo
- tagline – which is part of the company/corporate where it is an actual corporate tagline
- division or business unit name
- division or business unit tagline where true divisional tagline

A company must not include a product brand name, product tagline or a statement such as “from the makers/suppliers of [product brand or therapeutic category]” on a company-branded pen or notepad.

A company may sponsor a token cost conference satchel or bag or conference lanyard at a third party educational event. The satchel and lanyard would be considered utility items to be used at the conference and may be company-branded only (no product branding or product claims).

A company may also provide a token cost company-branded folder, satchel or bag for the purpose of carrying conference materials, educational material and/or company promotional material provided to delegates visiting a company trade display at an educational event, delegates attending a company educational event, members of an Advisory Board or delegates attending a clinical investigator meeting.

The provision of company/corporate-branded lanyards at educational events, Advisory Board or clinical investigator meetings are permitted to ensure that delegates wear their meeting identification for security reasons.

For guidance on permissible/acceptable company branding refer to the description above.

TABLE 3: PROVISION OF COMPANY BRANDED ITEMS (SECTIONS 2.6, 9.4.9 AND 9.5.9)

	Medical Education	Company Branded Pens and Notepads	Lanyards	Token Cost Bags	Brand Name Reminders (Not Permitted)
Company Educational Event	√	√	√	√	X
Third Party Educational Event A third party has the right not to allow a company to distribute these items	√	√	√	√	X
Advisory Board Meeting	√	√	√	√	X
Clinical Investigator Meeting	√	√	√	√	X
Trade Display	√	√	√	√	X
Medical representative detailing healthcare professional	√	X	X	X	X

FIGURE 17: COMPANY BRANDED NOTEPAD

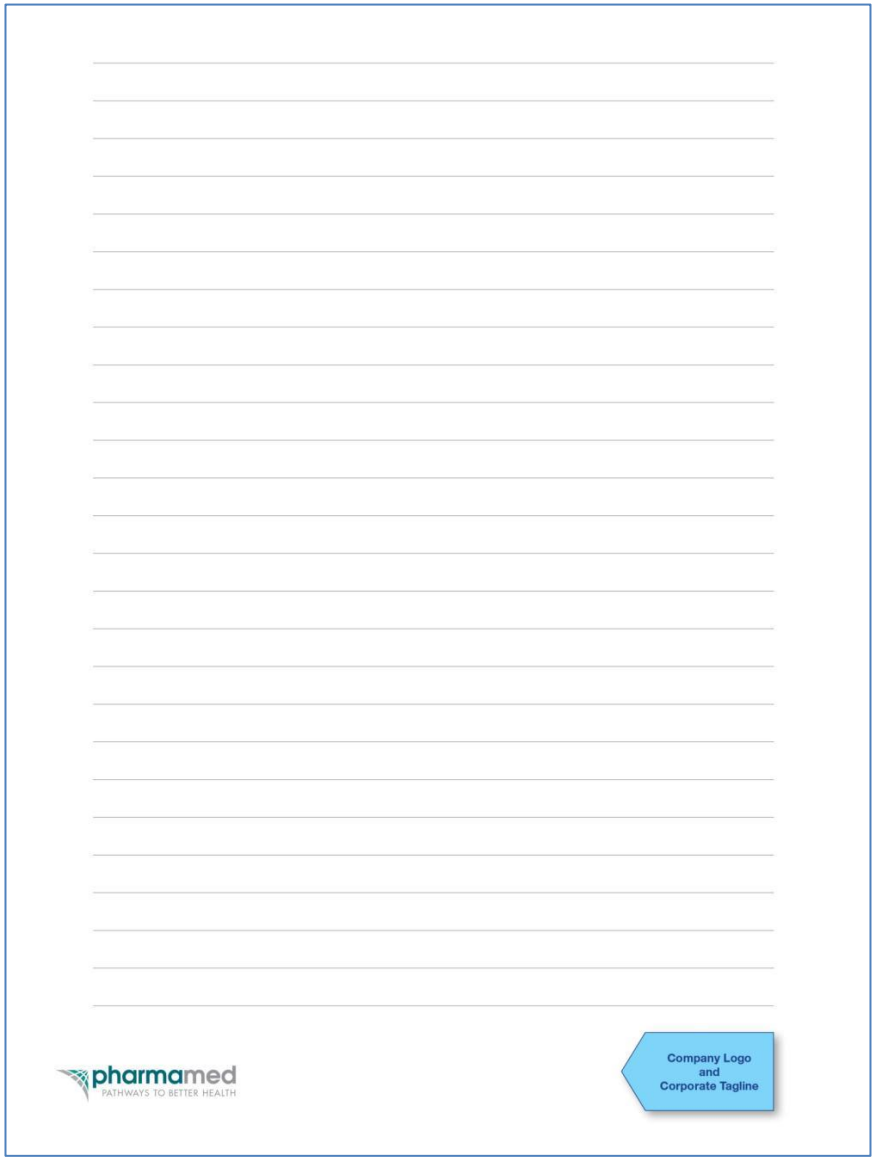
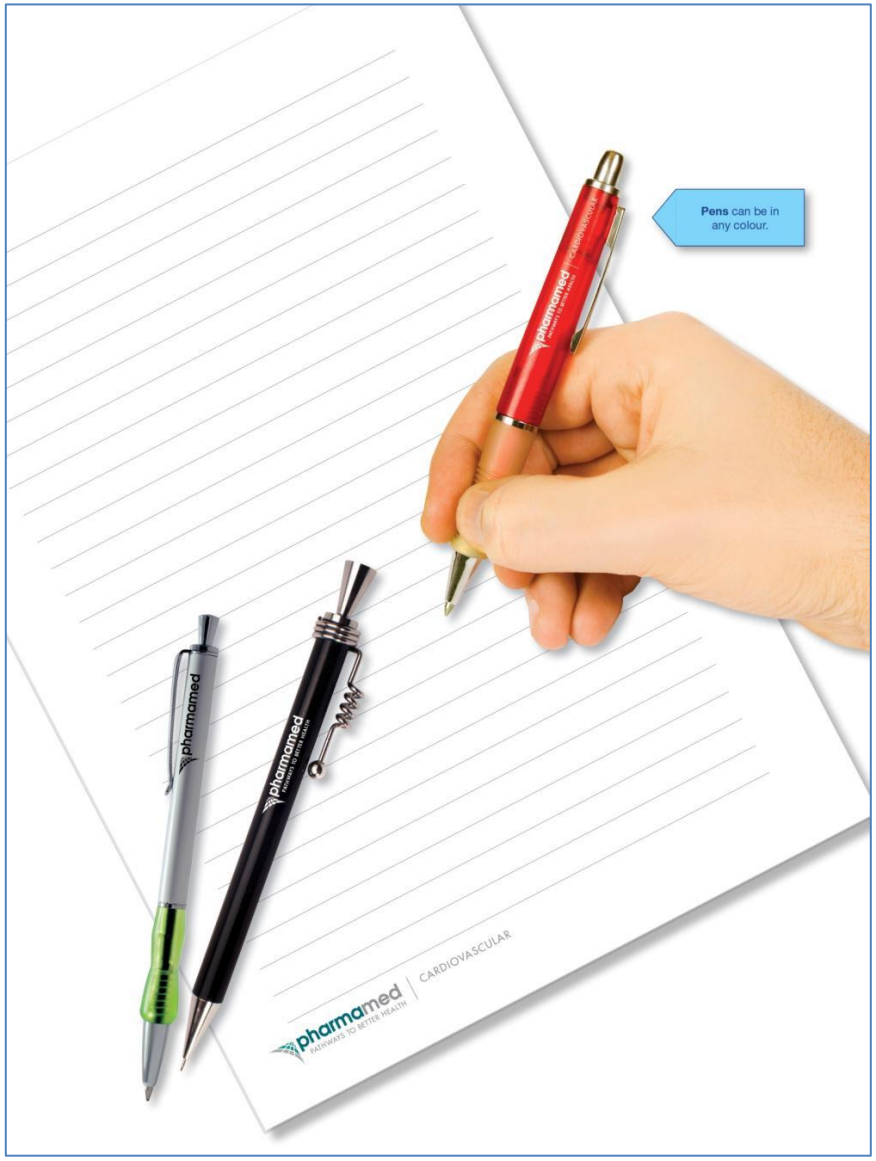


FIGURE 18: COMPANY AND CORPORATE DIVISION BRANDED NOTEPAD

FIGURE 19: NON-COMPLIANT COMPANY BRANDED NOTEPAD

FIGURE 20: COMPANY BRANDED PENS



Invitations to Company Educational Meetings

The following guidance is provided for company invitations and meeting agendas sent to healthcare professionals.

Use of a company template for educational meeting invitations would appear to offer good guidance on appropriate wording (refer to Figures 21A and 21B in these Guidelines). However, guidance should also be provided to representatives regarding the extent to which elements of the template may be altered. For example, the inclusion of images or graphics that emphasise hospitality elements (wine and food or venue photos) are not appropriate as these may give the impression that the provision of education is not the primary purpose of the meeting.

For meetings held after 1 October 2016 (Reasonable Expectations):

It is suggested that the following wording, or similar, be included prominently on meeting invitations, meeting registration websites, emailed invitations etc. where transfers of value will be provided for HCP attendees (i.e. airfares and accommodation costs) so that notice of the collection of personal information is provided in advance of registering for the meeting.

> *In accordance with Medicines Australia's Code of Conduct Transparency Reporting obligations, [COMPANY] is required to collect and publish the information as set out in the Collection Statement which accompanies this Invitation (the "Collection Statement"). If a Collection Statement is not included with this meeting Invitation please contact [COMPANY] immediately. In order for [COMPANY] to provide to you with the opportunity to review and correct such information, you are providing us with the following e-mail address to send this information to you: [insert HCP email address].*

The Monitoring Committee has previously noted that overall the quality of the agendas distributed for events could be improved. Many of the meeting agendas reviewed previously did not conform to the template provided in the most recent Code of Conduct Guidelines in that a specific breakdown of the event timelines and activities was not included in the agenda. Furthermore, the Committee noted that many of the responses allocated hours of education equivalent to the time scheduled for the event in its entirety, rather than the hours dedicated to the education components of the meeting. By way of example, the Committee noted a number of dinner events which ran from 7:00 pm to 10:00 pm, which claimed 3 hours of education, however a review of the agenda showed that the presentation and Q&A section consisted of 1.5 hours of the 3 hour event.

Information on the length of meetings, agenda, CPD points, hospitality and meeting templates

Although the duration of the educational session is important, other factors should be taken into consideration such as the value of the educational content, the speakers and educational material provided etc.

Many educational events that enable CPD points to be gained are evaluated by the RACGP prior to the awarding of points. The Monitoring Committee recommends that companies use the approved RACGP wording when indicating the number of CPD points on invitations or meeting materials.

Companies should use "Allocated a total of X CPD points x (Category 1) or X CPD points (Category 2) in the RACGP QI&CPD Program". The only alternative is "CPD points have been applied for" if the provider is waiting for approval by the RACGP.

Note that other professions may also award CPD points for accredited educational activities. Companies should use similar wording to the RACGP wording above, or refer to the wording required by the particular professional organisation.

The Monitoring Committee advises that the company should ensure that the invitation describes the educational content or meeting agenda in sufficient detail to allow a healthcare professional to be informed of the topic, speaker and duration of the education to be provided so they can assess the value of the educational event. As any hospitality provided in association with the meeting should be secondary to the educational component, this would also provide evidence to support this requirement of the Code.

It is also helpful to include an approximate finishing time on the invitation.

Photos of a venue should not be included on invitations as the venue should not be the primary attraction or focus of the meeting. An example of such an invitation can be found in Figures 21A and 21B in these Guidelines.

Information on invitations in relation to Partner or Travelling Companion Costs

Any travel costs of companions or family members attending an educational event must not be paid for or subsidised by companies. Therefore in relation to providing advice to healthcare professionals regarding partner payments, the use of the words 'partner contribution' may imply that the cost of a partner's attendance is partly paid for by the company. It is preferable to use wording that emphasises that the partner payment is for the full cost of their attendance.

Companies should take care that all costs incurred are covered by the healthcare professional or their guest. It is unacceptable for a company to claim after the event that they had "no control" over the accommodation costs of the guest and that those changes such as breakfasts, transfers and additional room charges were reimbursed by mistake.

It is recommended that invitations to company initiated medical education events state that hospitality can only be extended to invited healthcare professionals attending the medical education meeting as delegates.

The Code of Conduct Monitoring Committee has noted that some companies have attributed prohibition of certain activities to Medicines Australia. Companies should not misrepresent company policy as a Medicines Australia policy. Activities that are prohibited under the Code, for example payment for partners travelling with a healthcare professional who is attending an educational event, should be referenced to a statement such as:

> *"In accordance with the Code of Conduct for the prescription medicines industry in Australia, any costs (for example travel or meals) incurred by a partner/spouse, guest or family member travelling with a healthcare professional must not be paid for or subsidised by the company."*

The location of this wording is not prescribed in this document, however the Guidelines Working Group suggests that it is best placed on the RSVP section of the invitation.

FIGURE 21A: INVITATION TO A COMPANY EDUCATIONAL EVENT

This is an example of a 4 page invitation to a company educational event (front cover and back page). Invitations can be of any design. This example provides guidance on the content of an invitation only.

FIGURE 21B: INVITATION TO A COMPANY EDUCATIONAL EVENT

Figure 21b: Invitation to company education event (internal pages 2 & 3). This is an example of a 4 page invitation to a company educational event (front cover and back page). Invitations can be of any design. This example provides guidance on the content of an invitation only.

Pharmamed Australia has pleasure in inviting you to
(Name of Educational Event and information on topic/s and/or presentations)

Dr/Professor *(Name of Presenter/s with position/title or brief bio)*
will present

INVITATION

AN UPDATE IN CHOLESTEROL AND DIABETES

Date: Monday 23 March 2015
Venue: The George Restaurant
Address: 287 George Street, Brisbane, QLD 4000

Agenda:

6.00pm	Registration/Welcome
6.30pm	Presentation by *(Name of Presenter)*
7.00pm	Dinner
7.45pm	Presentation by *(Name of Presenter)*
8.15pm	Dessert and open forum with *(Name of Presenter)*
9.00pm	Close

PRIVACY STATEMENT
Insert your company's privacy statement here.

In accordance with the Code of Conduct for the prescriptions medicines industry in Australia, any costs (for example travel or meals) incurred by a partner/spouse, guest or family member travelling with a healthcare professional must not be paid for or subsidised by the company.

Total QA & CPD Points: 4 (allocated 2 points per hour Category 2)
(Ensure correct wording)

RSVP

Name _____
Phone _____ Fax _____
Email _____ QA & CPD Number _____
☐ Yes, I will be attending ☐ No, I am unable to attend
Special dietary requirements _____

Please RSVP to Dianna Smith by 16 March 2015
Telephone +612 8888 8888 Facsimile +612 9999 9999
Email dianna.smith@pharmamed.com.au

pharmamed PATHWAYS TO BETTER HEALTH | CARDIOVASCULAR

Important note: If an invitation includes a promotional claim about a product, the invitation becomes an item of printed promotional material and the requirements of Section 2 of the Code would then apply. Care should be taken when including a product brand name with a claim on an invitation to ensure that all relevant provisions of the Code are complied with.

The following wording should appear on the invitation: In accordance with the Code of Conduct for the prescriptions medicines industry in Australia, any costs (for example travel or meals) incurred by a partner/spouse, guest or family member travelling with a healthcare professional must not be paid for or subsidised by the company.

Section 9.6 Trade Displays

(See also Section1.4 Unapproved products and Indications and Section 4.1 Medical Educational Material)

Claims for products and indications approved in Australia must comply with the requirements of Section 1 of the Code. Any materials supplied for Australian-registered products must comply with all relevant provisions of the Code.

Promotion at International Meetings held in Australia

This section of the Code recognises the ability of companies to provide or display material for products or indications that are not approved in Australia at international and Australasian congresses as defined in the glossary of the Code.

The promotion of medicines at international meetings held in the Australia may on occasion pose certain problems with regard to medicines or indications for medicines which do not have approval in Australia although they are so approved in another country.

Financial support provided to the educational meeting organiser, or third party, for a trade display is regarded as sponsorship and must be reported in accordance with Section 41.3.5 of the Code. Appendix 3 in the Code provides the summary table required for reporting third party educational events sponsored by Member companies from 1 October 2015.

For international congresses, if a company wishes to display or have material available on a trade display regarding a non-Australian approved product or indication, this material must make it clear to a casual reader or passer-by that this product or indication is not approved in Australia. A statement on each piece of material to this effect and a prominent statement on the trade display where this material is being presented would satisfy this requirement. In the case of a trade display, the main display panels may be treated as one promotional item and include a single statement, prominently located, stating that the product/s or indication/s are not approved in Australia.

For products that are not registered in Australia (or indications that are not approved in Australia) the specific requirements included in Section 3 of the Code with respect to promotional materials do not apply, such as required wording for PBS information, inclusion of the Minimum Product Information on printed promotional materials etc. However, all materials should include the name of the supplier and the city, town or locality of the registered office; a clear and unambiguous statement for prescribers to review the product information (or equivalent document) before prescribing and that this information is available from the trade display.

For Australasian congresses held within Australia, it is also possible to display or supply material for products not approved for registration in Australia or non-Australian approved indications if that product or indication has received registration or approval in New Zealand.

When matters involving these activities have come before the Code Committee, it has been suggested that if a product is approved in Australia as well as internationally, it would be advantageous if any differences between the Australian indications and the international prescribing information document and the material being supplied at the trade display could be identified for the benefit of healthcare professionals. This could be done in a separate document that compares the two prescribing information documents and highlights any differences.

Companies should remember that there are a number of activities or items in addition to educational material that can be made available at trade displays including company-branded items (see Sections 9.4.9 and 9.5.9 of these Guidelines), medical educational material or complying hospitality. Other gifts or incentives provided by a company to encourage a healthcare professional to visit its stand at a trade display are prohibited.

Passport type activities, where participants at the educational meeting are encouraged to attend each trade display by the event's third party organisers in exchange for being entered in a competition to win a prize are acceptable. Companies should however be cognisant of the prize being offered by the third party organiser so as not to inadvertently bring the industry into disrepute.

Companies should also recognise the requirement in Section 9.6 of the Code that all activities in relation to trade displays must successfully withstand public and professional scrutiny and conform to professional and community standards. This includes the appearance and behaviour of company representatives such as their attire and general demeanour. Although not subject to a specific complaint, the dressing of company representatives in pyjamas was not considered to be appropriate by a Code Committee when it considered a complaint regarding another aspect of a trade display.

Section 9.7 Sponsorship of healthcare professionals to attend educational events

This section applies when companies sponsor healthcare professionals to attend either domestic or international educational meetings. The choice of healthcare professional must be based on the individual's interest in the area of medicine being discussed and their ability to communicate any relevant information gathered from these meetings with their Australian colleagues.

When agreeing to provide sponsorship of a healthcare professional to attend an Australian or international educational meeting (conference, symposia, workshop etc), companies should have a formal letter of agreement with the individual that will receive the sponsorship. This will provide documentation giving evidence of the ethical basis of the sponsorship and the transparency of the relationship, which benefits both the healthcare professional and the company. The letter of agreement should include the Collection Notice informing the healthcare professional of the company's obligations for the collection and publication of details about the sponsorship (see the Transparency Reporting Requirements and Figure 23 in these Guidelines).

It is recommended that a request for sponsorship to attend an independent, third party educational meeting be received in writing from the healthcare professional, detailing the educational meeting they seek sponsorship to attend, and how they will communicate relevant medical information gained at the conference to peers and other Australian healthcare professionals.

The healthcare professional requesting the sponsorship to attend an independent, third party educational meeting should undertake to share with peers and colleagues the benefit of knowledge gained through:

- supply the submission of a report or paper to the supporting company, and/or
- a written report to the relevant medical society and/or academic institution, and/or
- a verbal presentation to healthcare professionals.

Such papers and/or presentations must include a statement by the author/presenter acknowledging that financial support to attend the educational event was received, and such acknowledgement must identify the company/ies from which the support was received.

The company providing the sponsorship should formally respond to the request in writing, outlining the conditions/requirements underpinning the financial support, confirming that the sponsorship is solely for the healthcare professional to attend the educational meeting. Flights, transfers and hospitality can only be extended to healthcare professionals invited as speakers or delegates to the medical education meeting. The company letter should also note that the sponsorship is an opportunity to extend medical education for Australian physicians without any intention to induce, influence or reward the past, present or future prescribing, supply, purchasing or recommendation of any of the company's products.

The company should ask the individual to advise whether or not he or she has secured sponsorship from more than one company to attend the same event. The level of sponsorship provided by a company should take into account the cost of attending the educational event and whether sponsorship is to be provided by more than one company.

Section 9.7.5 Sponsoring travel to attend Australasian and international educational events

Companies may need to consider the practicalities of providing the healthcare professional's return flight if a delegate plans to attend subsequent educational events in other destinations independently of the company. This would enable the sponsoring company to adhere to the main principle of travel being provided by the most practical direct route.

The intent of the sections regarding travel arrangements is to allow reasonable time for a healthcare professional to travel to and from an educational meeting without providing additional time for leisure or sight-seeing whilst at the location of the meeting. A company may not fund or facilitate travel to or from a location so as to allow leisure time for the healthcare professional. This includes where the healthcare professional pays for their own accommodation at the destination or flight changes,

Section 9.7.7 Meals and beverages provided to healthcare professionals attending international educational events

The Code of Conduct states that the maximum cost of a meal (food and beverages) stated in Section 9.4.3 of the Code applies to hospitality provided to Australian healthcare professionals in association with an educational event held overseas.

Therefore, companies should plan that any meal (food and beverages) provided in another country complies with the monetary limit set by the industry association in that country (where applicable) or, if there is no monetary limit in that country, costs no more than AUD $120 (excluding taxes and gratuities).

As the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations is now implemented across Europe, each country now has set a maximum limit on food and beverages. Companies should comply with the limit in each country. The Spanish Pharmaceutical Industry Association, Farmaindustria, provides an interactive map with each country's hospitality limit: http://www.farmaindustria.es/idc/groups/public/documents/códigodocumento/farma_127513.pdf

The guidance is that if a company is arranging a meal in a country that does not apply a local limit on hospitality (for example, the US or Canada), you should plan for the meal to be less than AUD $120 at the exchange rate current at that time, with some flexibility 'built in'. For example, if at the current exchange rate the meal is AUD $100 or $110, but the Australian dollar weakens against the other country's currency between the date the event is arranged and the actual date, you would be able to demonstrate to the Monitoring Committee (if it asks for an explanation of the cost) that the meal was planned to be fully Code compliant and the exchange rate has resulted in a higher AUD cost. If the cost of a meal exceeds AUD$120 a company would need to be able to justify that the meal was compliant with the Code to the Monitoring or Code Committee.

Section 9.8 Consulting Arrangements and Section 9.9 Advisory Boards

Companies should be cognisant that a document summarising the purpose, objectives, justification of the size/number of Advisory Boards must be publicly available for scrutiny by the Code of Conduct Committee and complainant should a complaint be lodged Similar documentation is required for healthcare professional consulting arrangements.

It is not the intention of the Code, if a complaint is lodged, that confidential and commercially sensitive information would be disclosed to a competitor or other parties, but the documentation should be of sufficient quality to allow the Code Committee to understand the purpose, outputs, measures and responsibilities of those involved in these arrangements.

The Code of Conduct does not specify the number of healthcare professionals that would be considered reasonably necessary to form an Advisory Board. It is recommended that 8-12 would generally be appropriate. If a larger number of healthcare professionals is required, the justification should be outlined in the rationale for the Advisory Board.

Should a company consider that there is sufficient justification for forming more than one Advisory Board for an individual product, the reasons must also be outlined in the rationale for the formation of the multiple boards.

In relation to the provision of company branded items at an Advisory Board meeting please refer to Sections 9.4.9 and 9.5.9 of these Guidelines.

Section 9.10 Company supported medical practice activities

The Code recognises that the industry plays a vital role in supporting medical practice activities that enhance the quality use of medicines and patient outcomes. Where a company provides support for medical practice activities, such programs must not be offered or provided conditional upon any obligation to prescribe a particular product, switch to a particular product or for the purpose of gaining exclusive access to a medical facility.

When sponsoring practice/clinic/pharmacy/hospital staff, the overarching principle is that the activity should not bring the industry into disrepute. The sponsorship should not be construed as a gift or as an incentive to gain access to a practice; or an obligation to prescribe a particular medicine or switch patients to a particular medicine.

Sponsorship should not be provided to underwrite a commercial business or generate income for a practice. Sponsorship of staff in a practice, clinic or hospital should have clear guidelines outlining the role of the sponsored position and describing how the independence of the sponsored position/person from the sponsoring company will be assured. An activity where income is generated directly from a sponsored position would not be permissible. For

example a company could not simply sponsor a practice nurse for the purpose of conducting day to day practice/business activities.

In the same light, sponsorship of private institutions should be considered carefully. A request for funding to support better counselling of patients through the provision of tools which can be utilised by an organisation, or for educational programs would be acceptable. Activities which may have a financial benefit to the institution, such as reducing waiting times or length of stay, or funding for a consultant would not be appropriate.

Sponsorship could be provided to a 'not-for-profit organisation', for example to a shared diabetes educator or asthma educator for doctors within a Medicare Local or a position in a public hospital. A company could sponsor a number of nurses around Australia to assist in screening programs within the general practice setting. These programs should have a defined purpose to achieve better health outcomes and enhance the quality use of medicines and as well as predetermined timeframe, able to be justified by the clinical purpose. Care must be taken that these programs are not seen as direct or indirect inducements to prescribe a particular product, switch to a particular product or for the purpose of gaining exclusive access to a medical facility as these would bring the industry into disrepute.

A company could sponsor a nurse, to identify high risk patients for assessment and health management purposes, where the nurse provides limited assessment of these patients on the healthcare professional's premises and transfer of expertise and collation of the necessary data is performed to educate the practice staff and provide the healthcare professional with enough information for them to develop an appropriate plan of action.

The purpose of the sponsorship should be clearly outlined in the written agreement made with the healthcare professionals involved. For example it should be made clear that:

- the sponsorship is provided to support the prescriber to achieve better patient outcomes and not to replace the day-to-day activities of the practice staff
- at no stage should the nurse sponsored by the company take on responsibilities for which the prescriber receives remuneration, reimbursement or a financial benefit
- all clinical decisions, which may include the selection of appropriate medicines or the development of management plans, are the responsibility of the prescriber and the relevant allied healthcare professionals

Various additional elements that could be considered in any agreement between a company and an healthcare professional practice when providing medical practice support are included in a template in Figure 22 of these Guidelines.

See Section 9.7 of these Guidelines for additional guidance for sponsorship of healthcare professionals.

FIGURE 22: EXAMPLE OF A 'MEDICAL PRACTICE ACTIVITY AGREEMENT'

Pharmamed Supported Medical Practice Activity Agreement

Pharmamed *[insert your company name]* defines 'supported Medical Practice activities' as *[insert definition].* Company support cannot be provided to underwrite a commercial business or generate income for the practice or institution.

This agreement is entered into as of *(day)* of (*year)* ("Effective Date"), by and between

[Institution/Medical Practice] ("Recipient of company supported medical practice activity")

And Pharmamed [insert your company name], Australia

This agreement sets forth the terms and conditions under which the recipient of the medical practice activity will be supported by Pharmamed *[insert your company name]*.

Period of Support

The company supported medical practice activity will be provided for ([nsert period of support & instalment/milestones of payments if required].

Supported Medical Practice Activity Outline

Activity & any reviews required: [insert a brief outline of the planned activity]

Outline the support to be provided to the medical practice by XYZ Pharmaceuticals: *[insert a brief description of support to run the program/activity]*

Outline the recognition to be gained by Pharmamed *[insert your company name]* under this agreement: *[insert info]*

Dates/Location/s of support:

Publications

[Enter your company's publication requirements].

Payment [Please note payment may only be made to the practice/institution and not to an individual] [enter your company's requirements to be able to provide payment].

Confidentiality

[Enter your company's confidentiality requirements].

Disclosure

[Enter your company's disclosure requirements].

Privacy

[Enter your company's privacy disclaimer. Any patient level data that is accessible to the Company providing the financial support must be de-identified]

Disclaimer

Financial support for this medical practice activity is not conditional upon any obligation by the healthcare professional/s involved to recommend, prescribe, dispense or administer XYZ's product/s. This agreement must not interfere with the independence of a healthcare professional's professional practice.

[INSERT NAME OF Medical Practice]	Pharmamed [insert your company name]
Signature	Signature
Print Name/Title	Print Name/Title
Date	Date

Section 9.11 Grants and Financial Support

The Code recognises that the industry plays an important role in supporting healthcare professional activities such as medical research, education and training.

As described above, all interactions with healthcare professionals must:

- successfully withstand public and professional scrutiny;
- conform to professional and community standards; and
- have the primary objective of enhancing medical knowledge and the quality use of medicines in Australia.

If a complaint is lodged, it is not the intention of the Code, that confidential and commercially sensitive information would be disclosed to a competitor or other parties. However, companies should still be aware that a document summarising purpose, outputs, measures and responsibilities of those involved in these financial arrangements must be publicly available for scrutiny by the Code of Conduct Committee and complainant should a complaint be lodged.

See also Section 9.7 of these Guidelines for additional guidance for sponsorship of healthcare professionals to attend an educational meeting.

The template (Figure 22) in these Guidelines contains various elements that companies should consider when drafting agreements for financial support of medical practice activities. This template could be modified to suit other types of grants to healthcare professionals, research support, educational fellowships or any other financial support covered in Sections 9.11 and 9.12 of the Code.

Additional guidance on charitable or philanthropic organisations or events.

This section does not cover the industry's substantial sponsorship of philanthropic, cultural, educational, sporting and artistic activities or charities.

The Code recognises the importance of the pharmaceutical industry's support of these worthwhile activities and encourages industry participation. However the Code does require companies to consider several issues when they are considering providing sponsorship for charitable or philanthropic organisations or events.

When considering sponsorship opportunities, of primary importance to companies is the test of being able to withstand public and professional scrutiny and the ability to conform to any relevant professional and community standards of ethics and good taste. In addition, involvement in these activities must not be undertaken for product promotional reasons or for promotional purposes. Other sections of the Code will also need to be considered, particularly the prohibition of entertainment and the restrictions on any hospitality provided by the industry.

For example if a company is asked to sponsor a golf day, bike ride or fun run which has been designed to raise funds for a hospital, it should begin by asking whether this is a bona fide charity, assuring itself that the reason for involvement is not promotional and that the activity could withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste. The company would then need to examine any benefits it might derive from this sponsorship and whether these are acceptable under the Code. Discreet signage and recognition of the company name would be acceptable. However, for events that involve members of the general public the use of a product name would not be acceptable.

If the benefits from sponsorship involve a number of rounds of golf, these cannot be offered to members of the healthcare professions as this would contravene the requirement of the Code that prohibits the provision of entertainment to healthcare professionals.

If the event also involved a dinner that included entertainment and no educational component, similarly attendance at this event could not be offered to healthcare professionals. If, however, the entertainment was modest and there was a bona fide educational component to the dinner it might be acceptable to invite healthcare professionals to such an event.

A company may also sponsor a charitable event or organisation by providing a contribution (either cash or goods) towards a competition prize. In such instances the company should ensure the event and the prize are able to withstand public and professional scrutiny and the ability to conform to any relevant professional and community standards of ethics and good taste. Note such competitions are regarded as third party activities (see Section 2.7 of these Guidelines).

Section 9.12 Gifts and Offers

This section recognises the industry's primary role in providing current, accurate and balanced information about its products to healthcare professionals. It is not the role of the industry to provide healthcare professionals with gifts or offers. However the Code does recognise that the following items or opportunities are acceptable and are dealt with in the respective sections of the Code:

- Company-branded items of stationery (Sections 9.4.9 and 9.5.9)
- Educational material directed to healthcare professionals or patients (Section 4)
- Sponsorship to attend an educational event (Section 9.7)
- Hospitality at an educational event (Sections 9.4.3, 9.4.4, 9.4.5 and 9.5.5)

This section therefore prohibits the provisions of all gifts and offers that do not conform to these sections. The provision of non-product or company branded items other than those listed above would not be compliant with the Code. For guidance on the use of company branded items refer to Sections 9.4.9 and 9.5.9 of the Code and these Guidelines. Note that brand name reminders are no longer permitted under the Code (Section 2.6).

No gifts or offers should be provided to the families or employees of healthcare professionals.

Items such as gift vouchers, tickets to sporting/cultural events, cash or cash equivalents are not considered appropriate.

Section 9.13 Discredit to and reduction of confidence in the industry

Examples of activities that may be considered as bringing the industry into disrepute include:

- the provision of personal services or products to gain access to healthcare professionals, e.g. car washes, facials, etc.
- "educational" meetings that have hospitality as their primary purpose
- providing entertainment to healthcare professionals such as theatre tickets, or opportunities to attend sporting or artistic events
- activities such as "dine and dash" where opportunities are created to meet with healthcare professionals
- the provision of promotional material to members of the general public
- financial inducements to healthcare professionals to prescribe or dispense prescription medicines

Activities that would bring discredit upon the industry or reduce confidence in the industry will be treated as severe breaches and may attract a fine of up to $250,000.

Research

Clinical research

The Code explicitly includes provisions covering the appropriate interactions between a company and health professionals when conducting clinical research. The Code requires the same standards for these interactions as those required when interacting with health professionals who provide consulting services to a company as both are contracting arrangements. There is a prohibition on providing entertainment or payment or subsidy for the travel, accommodation or other expenses for a guest or family member of the researcher. Reasonable travel, accommodation or hospitality may be provided to clinical research personnel engaged in conducting research (See Section 10 of the Code, introductory paragraphs).

The Code does not cover the proper conduct of clinical research or clinical trials. However, the Code does identify the relevant Commonwealth therapeutic goods legislation and the NHMRC National Statement on Ethical Conduct in Human Research (2007, Updated March 2014) and other guidelines and policies that govern good clinical practice in clinical research.

Company branded items (pens, notepads, lanyards and/or bags) may be provided to healthcare professionals attending investigator meetings. For guidance refer to Sections 9.4.9 and 9.5.9 of these Guidelines.

Section 11 Ghost writing

This Code section is intended to ensure that companies are transparent about the contribution by companies and company personnel to authorship of a publication. If a company employee has been a co-author or author, this should be declared in the authorship list. If a company has contributed financially (for example, by engaging a medical writer) to the production of a publication, this should also be clear to a reader.

Section 12 Market Research

These provisions relate to direct company market research and market research commissioned by a company to a third party. Where a company purchases a market research report from externally commissioned or initiated research these provisions will not apply.

Section 12 of the Code is intended to make it clear that market research and competitions should not be confused. In the past the Code Committee has seen activities that are neither a complying competition nor a complying piece of market research. This may include some market research questions, such as seeking the number of patients presenting with a certain condition, followed by the opportunity to correctly answer another set of questions to be eligible to be entered into a prize draw. [Note that competition prizes are not permitted under the Code.]

Companies should take care to ensure that, if they are undertaking either activity, that each is run separately and that each activity complies with the relevant section of the Code. If market research data is being sought it is reasonable that some form of payment is made that is commensurate to a health professional's time and in accordance with business practice.

Any remuneration must be commensurate with the time expended.

A voucher to a healthcare professional must be valid only to obtain an item that is directly relevant to the practice of medicine or pharmacy.

This requirement also relates to market research commissioned by a pharmaceutical company. However, it is not expected that companies would examine any types of payment provided to a healthcare professional when purchasing an existing market research report produced by a third party that was not commissioned by a pharmaceutical company.

The overarching principle of all provisions of the Code is that entertainment or an item of entertainment must not be provided to a healthcare professional when participating in any activity covered by the Code of Conduct. See also Section 2.7 of these Guidelines dealing with competitions.

In a review of Market Research conducted by the Monitoring Committee in 2011, the Committee was pleased to see that the remuneration paid to healthcare professionals for participating in the market research was quite consistent across all companies, and that remuneration was commensurate with the time required to participate in the research.

The Committee also noted that some of the questionnaires did not identify who was undertaking the research – including where the research was undertaken by the company directly or a by a third party agency. The Code requires that it is clearly communicated to participants at the time of conducting the research that the research is being conducted on behalf of a pharmaceutical company. Additionally, the Committee noted that privacy statements should be communicated at the same time, and recommended that companies ensure that this occurs in each Market Research activity.

It was also noted that some companies have used recruitment agencies to recruit participants for their market research and highlighted potential issues which may arise if these agencies were not bound by the same Codes as a company or Market Research Agency. The Committee considered that to ensure consistent high standards in market research, any third party contracted by a company to conduct research or recruit participants, including agencies contracted by a market research organisation, must be bound by the same principles. Companies should ensure that their contracts with third parties include a clause to this effect.

The Committee also noted that where appropriate all contracts with market research providers should include provisions relating to adverse event reporting.

In its reviews of market research, the Monitoring Committee has noted that while most companies included privacy statements in their Australian market research, some statements were not adequate. The Committee has recommended that all companies should ensure that any privacy statement is consistent with the Australian privacy legislation and Australian Privacy Principles. A generic, international privacy statement might not meet local Australian legal requirements.

Section 13 Relationship with the General Public

Section 13.1 General Principles

Pharmaceutical companies may provide information to the general public in a variety of media. Companies must act responsibly by meeting the information needs of the general public by the provision of current, accurate and balanced information about diseases or conditions and prescription medicines available in Australia.

The following information is an extract from the Therapeutic Goods Act 1989 (Cth)

> **"Chapter 5** Advertising, counterfeit therapeutic goods and product tampering
>
> **Part 5-1** Advertising and generic information
>
> **Division 3** General provisions about advertising therapeutic goods
>
> 42DL Advertising offences
>
> (1) A person must not publish or broadcast an advertisement about therapeutic goods:
>
> that refers to goods, or substances or preparations containing goods, included in Schedule 3, 4 or 8 to the Poisons Standard…… ."

Section 3 of the Act defines an advertisement:

*"**advertisement,** in relation to therapeutic goods, 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."*

The Code reflects this legislative requirement that prohibits the promotion of prescription medicines to members of the general public. The Code also recognises the need by members of the general public for information regarding prescription medicines and the requirement for the industry to meet those needs in a responsible and appropriate manner. The Code provisions are designed to establish a framework in which this information can be provided to members of the general public in a non-promotional and educational manner.

The test under the legislation is whether the information, when objectively assessed, is intended directly or indirectly to promote the use or supply of a particular product. Companies must be aware that if information published (in any media) by them about their products can be accessed by members of the general public (in any media), there is always a risk that the publication could be said to promote the use or supply of a particular product.

This will be the case even if the publication adopts a general and educative approach of the kind described in the Code.

The Medicines Australia Code Secretary is often asked if medical students (or other health professionals in training prior to registration) should be regarded as health professionals or members of the general public. The Therapeutic Goods Act 1989 (Section 42AA) permits the advertising of prescription medicines to medical practitioners, pharmacists, nurses etc. It is generally understood that a person is not a health professional as recognised under the Act until they have completed the required training and become registered in their profession. Whilst promotional activities must not be developed for, or directed to, a medical student or other student health professional, in the learning environment they may in certain circumstances observe promotional activities being delivered to registered healthcare professionals.

Refer also to Section 9.1 of these Guidelines.

Section 13.1 of the Code states that all statistics or analyses provided to the general public must be referenced to their source. The intent is that when specific claims are made, for example regarding the incidence or severity of a disease, the reader is provided a reference to substantiate the claim. The reference does not need to be linked directly to text in the piece; it may appear at the end of the piece under a descriptive heading, for example "Disease prevalence statistics from Jones el al Epidemiology 2016; 1(1); 123-126". Generally statements regarding diseases that the reader would reasonable understand and be familiar with do not require referencing. Examples of statements that would not require referencing are "Cardiovascular disease is a leading cause of death in Australia" and "Regular exercise is beneficial to overall wellbeing".

Section 13.4 Product Specific Media Releases

Section 13.4 of the Code describes how the pharmaceutical industry can act responsibly and meet the information needs of the general public by using a media release to provide current, accurate and balanced information about products available in Australia. 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.

A company is responsible for all material prepared for the media whether it is prepared in-house or by an agency it engages.

Product specific media releases have a number of requirements under the Code. Audiovisual materials that may accompany a full media release, such as audio grabs, need not include mandatory statements if this is not practicable. However, these may not be issued without the full media release that includes the mandatory requirements.

Before any product specific media release is issued directly, or through conferences for the general public media, to announce a new product or indication, the product must be registered in Australia and the company must have taken reasonable steps to inform the medical and pharmacy professions of its availability.

Note that announcement/s of a new product, new indication or PBS listing are the only circumstances in which product specific media releases for the lay media are permitted. In consultation with the TGA a company may issue a media statement about product safety or product recall or withdrawal.

Any quotes from a healthcare professional or member of the general public used in a press release must comply with the Code. The Guidelines Working Group recommends that companies consider including a short statement on a media statement that outlines the relationship between the company and a healthcare professional spokesperson. It suggested the following wording could be used for such disclosure:

“Dr. X has served on advisory boards and been involved in clinical trials sponsored by [Company Name] for which compensation was received. In relation to this [Company Name] media announcement, no compensation was provided to Dr X, and the opinions expressed are their own. Dr X has been briefed by [Company Name] on the approved use of this product.”

As required by section 13.4.1 of the Code, product specific media releases must include a summary of the side effect profile, product’s precautions, adverse reactions, warnings, contraindications and interactions consistent with the Minimum Product Information. This information must be included in the body of the media release. The intent of this summary is to provide balance, and as such companies should endeavour to include those components most relevant to the general public. In preparing a summary, as noted above, companies should consult the product CMI for relevant content and appropriate language.

In considering complaints about the promotion of products or indications not approved in Australia, the Code Committee has determined that “responding to key international developments such as major clinical trials” should not be interpreted to mean that proactively distributing a media release to the general public media in Australia is acceptable.

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.

As with all complaints against prescription medicine companies, the Code Committee only has the purview to review the activities of the company and not the media outlet. Should a media outlet obtain a pack shot from an alternative source, for example a pharmacist, the company would not be held responsible.

The media release must be made available upon reasonable request. The request may be made by anyone, and the “reasonableness” of the request can be considered in terms of how quickly the release must be supplied or how many copies are requested, etc, rather than whether the request per se is reasonable.

Companies have a duty of care to ensure the Media has access to accurate information at the time of media releases as described in 13.4.1 of the Code and associated Guidelines.

If changes are warranted to embargo materials, these should be addressed as soon as practical prior to the release date. This may involve the withdrawal, replacement or correction of materials. Once the embargo is lifted and the materials are released, no other product specific media releases are permitted as described in section 13.4.2 of the Code.

Section 13.5 General Media Articles

Pharmaceutical companies or their appointed agents must not initiate stories on products or promote prescription medicines to the general public.

The Code Committee has commented that the media would have access to published information on significant clinical trials through Reuters and other media wire services and may contact a company for information or write an

article based solely on an article published in a scientific journal. The Code Committee stated that there is a clear difference between a pharmaceutical company and another independent entity initiating a media release about a new or unapproved prescription medicine.

If it is asked to comment or provide a response a company must not embellish upon the original article or seek to promote a prescription medicine.

If a media outlet approaches a pharmaceutical company for comment on a newly published study relating to a prescription medicine, whether an approved product, non-approved indication or non- approved product, the company may respond in a balanced, accurate and non-promotional manner.

As with all complaints against prescription medicine companies, the Code Committee only has the purview to review the activities of the company and not the media outlet. Should a media outlet obtain a pack shot from an alternative source, for example a pharmacist, the company would not be held responsible.

Section 13.6 Educational information available to the general public

Medicines Australia encourages companies considering making information about its products available to the general public under the provisions of this section to contact Medicines Australia to discuss these activities, or to seek their own legal advice.

Examples of patient educational material which could be used include:

- Patient information about a medical condition which may discuss all medically important treatment methods but only in very broad terms (no emphasis on any one product). This type of material could be distributed directly to the general public as a “community service”.
- Patient information about a medical condition or specific treatment (not brand name) which is prepared in conjunction with the relevant professional society and is endorsed by that society. This type of material may be distributed to the general public, as a “community service”. However, the endorsement of a professional society does not preclude a finding of a breach of this Section if the other provisions of this Section are not fulfilled.
- General information on medical advances in healthcare. This could include information on the discovery of new drugs, and research plan of the individual company, but that material must satisfy general interest and not promotional purposes.

Care should be taken when conducting disease awareness that it cannot be construed as advertising. The presentation of a disease awareness campaign must reflect the severity and prevalence of the disease in the community (that is, the disease should not be portrayed as being more serious or more prevalent than it actually is) and consistent with the current body of evidence.

Where an AAN/generic name of a prescription medicine forms part of the public communications about a medical condition or its treatment, particular care needs to be taken, for example, where a hormone is used to treat a hormone deficiency. There should be no undue emphasis on that generic name/AAN because this might be construed as advertising a treatment for the disease. Examples of complaints concerning this type of disease awareness activity are complaints 1016 and 1045, which may be reviewed in the 2010 Code of Conduct Annual Report (complaint 1016) and the 2011 Code of Conduct Annual Report (complaint 1045).

Section 13.7 Materials for use with patients (Patient Aids)

Materials (patient aids) that will be used by the patient inside their home and can only be used for the intended purpose may be product branded. For example, instructions on how to inject a product can be branded with a product name.

If materials are likely to be used outside the home, for example a cooler bag for an injectable product, or used for purpose other than that originally intended, they should not be branded with a product name. They could be branded with the Patient Support Program name provided this does not include a product name or with the company or business unit branding provided it complies with all applicable regulations and legislation requirements.

Patient Aids that are not product specific includes items such as sharps containers, a medication compliance dose aid. If such items are intended to be made available to patients who have not been prescribed a particular product, they must not be product branded.

It is permissible to include a ‘with compliments slip’ with patient aids or Patient Support Program materials with the company name and/or logo.

Mobile Media Platforms and the use of Applications (Apps)

Companies may develop patient aids in the form of Apps for mobile media platforms (e.g. iPhone and iPad, Blackberry, Android based smart phones and other tablets). Patient aids in the form of Apps that are solely intended to provide information for the patient once a decision to prescribe that product has been made, may be product specific. The content of such material must be designed to assist with patient compliance by providing information, which clarifies method administration, precautions, special instructions, and similar information. It must not make comparisons between products or include promotional claims. The Apps for mobile media platforms are available to the general public via the devices application store (eg. iTunes store, Google Play store or a non-secure website). The App should therefore be password protected upon initialisation. The password to gain access to a restricted App should not be a word that would be easily identifiable, such as a product name.

QR Codes

A company may wish to provide patient aids to patients who have been prescribed a product via QR Codes which link directly to applications or microsites. If the destination of these links is visible to the general public (eg. iTunes store, Google Play store or a non-secure website), then a mechanism such as a password protected application/ microsite or other entry system would comply with the requirements of this section. The password to gain access to a restricted application/microsite should not be a word that would be easily identifiable, such as a product name.

Section 13.9 Use of the Internet

The internet is one of the channels of information available to members of the general public and all provisions of the Code relating to the relationship with the general public apply.

To allow a reader to identify the source of information provided on a website the company name must appear on the home page of any site developed by a pharmaceutical company. This includes sites for patients and the general public. In the case of a sponsored site, an acknowledgment that it has been prepared with assistance through an educational grant from company X should be included on the home page of the site. This might include, for example, a health consumer organisation website that has been developed with financial assistance from a pharmaceutical company.

Access to websites designed as patient support programs, that is, a program for a patient already prescribed a particular prescription medicine, should also be via a password or other entry system. The password should not be a word that would be easily identifiable, such as the product name. A password such as the AUST R number from the medicine pack would be acceptable.

In developing a website or source of information under Section 13.9 of the Code it is envisaged that a company should be able to develop a brief non-promotional summary of its prescription medicines. The format of the information contained in MIMS Abbreviated is suggested as an appropriate template, given that it includes a balanced description of the key aspects of a product and is based on the approved Product Information.

The wording and terms used in this summary must, however, reflect the audience to which it is targeted, which may not enjoy the same level of medical or technical knowledge as readers of MIMS Abbreviated.

In addition, companies are encouraged to include a copy of the Consumer Medicine Information (CMI) on their websites. Again, this information has been designed specifically for consumers and is in a format that provides valuable information regarding prescription medicines. The CMI should be published in its entirety, suitably identified as a Consumer Medicine Information document, and must not be embellished, for example by including a logo or promotional devices.

A disease education activity that makes no mention of specific prescription treatments but includes a website address that contains the name of a specific prescription medicine could be considered as promoting that product to members of the general public. Similarly, a company website should not provide disease state information linked to or in association with the company's prescription products. 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.

The development of a website that contains a product name in its address and contains its CMI, for example, may be appropriate if it is not linked to other activities that may fail the test of intent.

Section 13.9 of the Code also allows linkages to other reputable information sources that will enhance a member of the general public's understanding of a disease area. For example, this could be a linkage to a patient support group, health consumer organisation or a site that is devoted to non-promotional information on a particular disease state.

Companies are advised to take particular care when including references or links to other information sources, to ensure they are aware of the information in those other internet sites and to stay informed of any changes to that information**.** If the information accessed through the link is intended directly or indirectly to promote the use or supply of a company's products, the reference or link should not be made.

An Australian pharmaceutical company may provide a link from their home page to the parent company or global home page. An Australian pharmaceutical company may provide a link from the Australian news page/media releases section to the parent company or global news page/media release section, however a link cannot be made from the Australian site to a specific media release. A specified disclaimer must appear prior to opening the link (see next paragraph). A company could not provide a link from the Australian company home page, disease state website or patient support program website to any site promoting a medicine.

The Code also requires that when making these references and linkages a clear screen should be displayed showing certain specific disclaimers:

- that the information the reader is about to access may not comply with the Australian regulatory environment and that readers should refer to the CMI to fully understand the Australian regulatory approval;
- that the intent of providing this material is to inform and not to offer advice; and
- any information provided should be discussed with the reader's healthcare professional and does not replace their advice.

Companies should note that these disclaimers may not protect a company from breaching the Therapeutic Goods Act if the linked site includes material which is found to constitute an advertisement for the company's product.

Medicines Australia encourages any company considering making information about its products available to the general public under the provisions of this section to contact Medicines Australia to discuss these activities, or to seek their own legal advice.

Pack Shots

The inclusion of a pack shot on a publicly accessible company website together with information about the medicine may be deemed to be an advertisement and therefore in breach of the Code. A company may include information such as a Consumer Medicine Information (CMI) or Product Information (PI) as this is not considered promotional.

A pack shot can be included on a restricted access patient support program website as the patient has already been prescribed the medicine or on a restricted access site for healthcare professionals.

Refer to TGA Guideline on Price Information Code of Practice: http://www.tga.gov.au/industry/advertising-picop.htm

Section 13.10 Social Media

The current provisions of the Code of Conduct pertaining to promotion to healthcare professionals (Section 2) and promotion to the general public (Section 13.3) apply to social media.

Information placed by Australian pharmaceutical companies on social media such as YouTube, Facebook, Twitter or blogs must adhere to the Australian regulatory requirements, that is, prescription medicines must not be advertised to the general public.

All Companies should have policies and procedures which describe the roles and responsibility of its employees when interacting in the social media space to ensure that employees comply with the Code of Conduct.

Since the rise of the social media, companies have experienced heightened interest and awareness of their responsibilities in these media regarding the prohibition of promotion of prescription products to the general public and adverse event reporting. Companies providing information via social media platforms should apply the principles of Section 13 of the Code. Engagement with the general public through social media and the internet must not bring discredit upon, or reduce confidence in the pharmaceutical industry.

There are two broad social media scenarios:

- company initiated and controlled activities; and
- sponsorship of a third party (such as a health consumer organisation) to develop a social media portal.

Companies have full responsibility for their own initiatives. Through their contracts with third parties, the responsibilities of each party should be described.

Companies who engage in social media activities that include discussion boards and sharing of audio and visual content should consider:

- whether discussion boards need to be monitored and how regularly;
- how to manage inappropriate conversation;
- establishing rules for participants joining a discussion forum that:
- outline what is inappropriate conversation (e.g. offensive language, racist comments, promotion of a product) and that conversations may be monitored;
- describes whether any content would be excluded, and the process for excluding it;
- discussion boards may be shut down at any time;
- responsibilities for reporting of monitoring and reporting of Adverse Events reported via this media,

In accordance with Section 13.9 of the Code, when providing a link to a Social Media site, a clear screen should be displayed showing certain specific disclaimers:

- that the information the reader is about to access may not comply with the Australian regulatory environment and that readers should refer to the CMI to fully understand the Australian regulatory approval,
- that the intent of providing this material is to inform and not to offer advice, and
- any information provided should be discussed with the reader's healthcare professional and does not replace their advice.

Section 14 Relationships with Health Consumer Organisations

Sponsorship of Health Consumer Organisations and educational grants

Heath 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. Organisations such as charities, foundations and healthcare professional organisations involved in research activities relating to a particular medical condition would not be a determinate of a HCO.

** NOTE (19/01/22) - The list published below is no longer relevant, and Medicines Australia no longer publishes a list of confirmed or approved Health Consumer Organisations. Instead, see Section 12 of Code Edition 19, as well as the Glossary in Edition 19 for how a HCO is defined*.

The following are examples of HCOs (not exhaustive):

- Rare Cancers Australia
- Kidney Health Australia
- Hepatitis Australia
- Arthritis Australia

The following organisations (not exhaustive) are not considered to be HCOs because these organisations are not consumer-led and/or representing the views of consumers. This is not to suggest that these organisations do not provide valuable services or advice to consumers. Further, the question is not whether an organisation has charity status for taxation purposes. The determination of whether an organisation is a HCO relates to the direction and management of the organisation being by consumers and that the organisation represents consumers' views.

- Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM)
- Australian Lung Foundation
- Australian Leukaemia and Lymphoma Group
- Collaboration for Health in Papua New Guinea
- Haematology Society of Australia
- Influenza Specialist Group
- MS Research
- RANZCO Eye Foundation
- Skin and Cancer Foundation
- Sydney Children's Hospital Foundation

Reporting direct/indirect financial support to HCOs

The intent behind reporting of HCO support is to provide transparency about relationships between a pharmaceutical company and a HCO, which is covered under section 14 of the Code. It is not intended to capture every donation that a company makes to a charity or HCO where there is no relationship between them.

Each company must provide to Medicines Australia for publication on its website, a report listing health consumer organisations to which it provides support and/or significant direct/indirect financial support.

The following are examples of reportable support and significant direct/indirect financial support that must be reported. These examples are also illustrated in Table 4 below:

- Volunteering sales representatives' time to distribute leaflets to HCPs on behalf of the HCO
- Providing a grant of $5,000 to a HCO to produce 2000 booklets to assist patients take an active role in managing their condition
- Sponsor a (non-healthcare professional) HCO representative to attend an educational meeting in London
- Sponsor or purchase a corporate table at an annual fundraising dinner

The following examples of support that would not be reportable:

- Sponsoring a company employee to participate in a fun run who decides in their personal capacity to donate the raised funds to a HCO.
- Company employee volunteering to assist a HCO

- Employee donations as part of a salary sacrificing arrangement
- Sponsoring a HCP to participate in a fundraising event as part of a HCO charitable event – the funds are paid directly to the HCO (when the company has no influence over the selection of the HCP)
- Sponsoring a member of the public to participate in a fun run for charity where the funds are transferred directly to a HCO

The Monitoring Committee has reviewed companies' HCO support reports for calendar years 2013, 2014 and 2015. Overall, most companies had provided good descriptions of their support for HCOs, which provided sufficient detail to gain an understanding of its purpose. However, the Monitoring Committee considered that some companies had not provided sufficient information in their reports to meet the requirement (Section 14.4 in Code Edition 17, Section 41.1 in Code Edition 18) for "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". Some descriptions were very brief, or non-specific. For example, the descriptions "educational grant", "unrestricted educational grant", "financial support towards running costs" or "to support education and training" were considered inadequate to enable a reader to form an understanding of the purpose of the funding support.

The following are some examples where companies had provided brief, but adequate information about their HCO support:

- "An educational grant to Arthritis Australia to host a 4th Steering Group meeting for the 'Time to Move' project and completion of a resultant White Paper publication"
- "Grant to support preparation of Rare Cancers Evidence Report - printing, distribution and launch costs"
- "Funds to produce 10,000 Macular Degeneration A4 booklets in May to assist patients with their condition"

The *"Working Together – A Guide to the relationships between health consumer organisations and pharmaceutical companies"* is a useful tool for both parties when entering into a sponsorship arrangement. It is available from the Medicines Australia website at https://medicinesaustralia.com.au/community/working-together-guide/

Sponsorships

Companies must ensure they have documented the way in which they provide sponsorships and the criteria they use based on the requirements of this Code and be fully aware of what their sponsorship funds will cover.

Educational Grants

In providing an educational grant a company must be aware of what this grant will cover. The company providing the education grant must not direct or influence the health consumer organisation, however as stated in Section 14.3 of the Code they may correct any factual inaccuracies.

TABLE 4: EXAMPLE REPORTING TABLE FOR SUPPORT FOR HEALTH CONSUMER ORGANISATIONS (HCOS)

(ongoing from Code Edition 17 and for the duration of Code Edition 18)

Note: Examples are intended to assist with the development of a report only. The names of HCOs are fictitious. Descriptions will vary.

Reporting period: 1 January 2016 – 31 December 2016 **(reported annually by Medicines Australia by 30 June)**

Company Name: XYZ Pharmaceuticals

Examples of SIGNIFICANT for reporting in the HCO Reporting Template			
Name of Health Consumer Organisation	**Description and/or purpose of support**	**Nature of support – monetary value (or equivalent) or description of non-financial support**	**Notes for example only**
Pink Ribbon Council	Distribution of Pink Ribbon Council patient leaflets to healthcare professionals by sales representatives	Volunteering of staff time	*Unless express additional costs are incurred (eg payment for printing of leaflets), no equivalent monetary value is required in "Nature of support".*
Arthritis National	Funds to produce 5,000 booklets assisting arthritis patients to take an active role in managing their condition	$5,000	*If HCOs receive more than one form of support, the cumulative description of all support must be sufficiently detailed to enable the average reader to understand the nature of all of the support.*
Mental Illness Foundation	Opportunity to attend capacity building skills workshop for HCOs (facilitated by global company)	Per delegate meeting cost and travel equivalent to $5,120	*If multiple HCOs have been provided with the same support (eg all attending the same workshop), the support must be listed for each HCO The costs must be apportioned appropriately.* *If support is for attendance at a global event (hosted and paid for by a global headquarters), only the monetary value (or equivalent) incurred by the Australian company to support the HCO attending the event must be reported (eg report any direct and/or transfer costs borne by Australian company).*
Eye Health Australia	Purchase of a corporate table at annual fundraising dinner	$1000	*All significant financial and non-financial support to HCOs must be reported, regardless of who benefits from support (eg the company, patients, and/or healthcare professionals). Please note that companies are prohibited from inviting HCPs to attend fundraising dinners.*
AsthmaTeen	Packing of HCO bandanas to support fundraiser	Volunteering of staff time	*Unless express additional costs are incurred (eg packing material costs), no equivalent monetary value is required in "Nature of support".*

Examples NOT SIGNIFICANT for reporting in HCO Support Reporting Table			
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**	**Notes for example only**
Arthritis Foundation (AF)	Assistance in developing research project brief and appointing agency for the project (in close liaison with AF)	Volunteering of staff time	*Volunteering of staff time would not be considered significant for reporting purpose. However, if a company provided its agency to do the work on its behalf, the monetary value (or equivalent) of the agency's time would be considered significant for reporting.* *No company must seek to influence HCO materials in a manner favourable to its own commercial interests.*
Cancer Unite Australia	Donation of corporate meeting space for fundraising event.	Donation of corporate meeting space	*Donation of the use of company facilities, without the incurrence of any additional costs (eg audio-visual services, catering costs, etc.), would not be considered significant for reporting purposes.*
Skin Cancer Network	Healthcare Professional member of Skin Cancer Network participates in a steering committee for a disease awareness website	Flights and accommodation	*This would be reported as a transfer of value to the individual HCP.*
Australian Heart Council	Member of Australian Heart Council participates in an Advisory Board	Flights, accommodation and hospitality	*If the Heart Council member is a HCP, this would be reported as a transfer of value to the individual HCP. If the Heart Council member is not a HCP (e.g. a consumer), there is no requirement to report the transfers of value to the individual Council member.*

Section 17 Patient Support Programs

Disclosure of payments to healthcare professionals

Any payments made to healthcare professionals for facilitating, enrolling or educating patients in a Patient Support Program must be declared to consumers on the enrolment form. This includes both hard copy and electronic enrolment forms. Any payment made must be commensurate with the time involved to complete each task. Where a company has negotiated an individual rate of payment with a pharmacy group and/or healthcare professional that negotiated rate must appear on the materials used by that group/individual. If a company uses a sliding scale for payments (e.g. first 10 enrolments at $5 each, subsequent enrolments $3.50 each) the disclosure on the enrolment form can identify the range of payments offered.

Example templates for disclosure of payments:

- "[COMPANY X] has offered a fee of $x for facilitation of enrolment in this program"
- "[COMPANY X] has offered a fee ranging from $x to $x for facilitation of enrolment in this program"

It should be ensured that Patient Support Program enrolment strategies requiring changes to TGA approved trade packs (for example, a package insert or a change to labelling) comply with the Australian regulatory requirements for prescription medicines.

Questions can arise about whether a company may make a HCO aware of the availability of a Patient Support Program for a specific medicine. This would be appropriate as long as the company or the HCO are not using the availability of the Patient Support Program in a manner that encourages patients to seek a prescription for the medicine, which would be regarded as promotion of the medicine to consumers.

A company may include a package "onsert" or "insert" within a Product trade or starter pack to provide non-promotional information about the availability of a Patient Support Program and how to enrol into the program. Any information must comply with Sections 13.3 and 13.6 of the Code.

A package "insert" is anything inserted inside the product packaging, for example a leaflet. An "onsert" is anything affixed or otherwise attached to product packaging.

Whether using an insert or onsert, a package enrolment form must state "The Patient Support Program is not authorised or approved by the Australian regulator of medicines, the TGA". It is expected that these words are included verbatim.

A package insert or onsert that directs patient to another location where they can enrol in the Patient Support Program, such as to a website, or, if text on the primary package directs a patient to a location where they can enroll in a Patient Support Program, such as by providing a URL or a QR code, wherever possible it should be clear to the patient that the Patient Support Program is not authorised or approved by the TGA using the text described above. Where there is insufficient room for this text on the onsert or insert, then a statement to this effect must be prominently displayed or clearly communicated to the patient **prior** to them enrolling into the Program.

If there is an insert or an onsert strictly limited to directing a patient to enrol in a Patient Support Program, there is no requirement for these to be reviewed or approved by the TGA. The exception to this is where the onsert obscures the package labelling in any way, which would require TGA review.

Section 19 Discredit to and Reduction of Confidence in the Industry

The Code is also relevant for information provided to patients and/or Health Consumer Organisations with respect to the Pharmaceutical Benefits Advisory Committee (PBAC) process.

Transparency Reporting Requirements

Medicines Australia is a strong advocate for transparency of payments and benefits provided by the Australian medicines industry to health consumer organisations and healthcare professionals. The purpose of disclosure of payments and benefits is to demonstrate our ongoing commitment to this endeavour. It is our hope that this disclosure will help the general public to better understand the nature and extent of programs we support in the interest of increasing quality use of medicines, advancing patient care and supporting our local communities.

For this reason, and to ensure continued public confidence in these relationships, the Code of Conduct includes requirements for reporting of payments and benefits to healthcare professionals (e.g. speaker fees, consultant fees, and advisory board member fees) and greater disclosure of the nature of our relationships with health consumer organisations.

This section of the Code Guidelines brings together all advice relating to transparency reporting under Code Edition 18.

- **Part A** describes the new requirements for reporting transfers of value to individual healthcare professionals that commenced on 1 October 2015.
- **Part B** describes reporting requirements that continue from Code Edition 17 and for the duration of Code Edition 18:
    - Health Consumer Organisation Support reports.
- **Part C** describes the requirement for reporting sponsorship of third party educational meetings and symposia from 1 October 2015.

TABLE 5: SUMMARY OF REPORTING REQUIREMENTS

The following table summarises the reporting requirements under Code Edition 18 and the dates that reports are due to be submitted to Medicines Australia and/or published.

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 Professionals Payments and Transfers of Value 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
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

* Note this report will include BOTH payments and transfers of value published with consent and published under reasonable expectations. That is, a single, combined report.

A. Reporting Transfers of Value to healthcare professionals from 1 October 2015

NOTE: There are detailed Frequently Asked Questions and Answers later in this Section in Table 10.

From 1 October 2015, companies are required to report payments and transfers of value to healthcare professional individually. The Code requires reporting the following payments and transfers of value:

- Fees paid to healthcare professionals (or to their employer or a third party organisation) for:
  - speaking at an educational meeting or event;
  - consulting services;
  - attendance at an Advisory Board meeting;
  - participating in market research where the identity of the healthcare professional is known to the company.
- Airfares for travel both within and outside Australia
- Accommodation provided whether in Australia or another country
- Registration fees to enable attendance at an educational meeting

Companies are required to report payments or transfers of value in accordance with the template which is provide as Table 9 in these Guidelines. The table requires reporting of all individual payments or transfers of value for each healthcare professional, providing 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 – see all alternatives in the table below);
- 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. **Goods and Services Tax:** Note that all payments and transfers of value should be reported exclusive of GST**.**

The template provided in these Guidelines is in a table form and requires reporting of all individual transfers of value for each healthcare professional by providing the following information in the following format:

Data element	Data Format
Date of the event or provision of service	Date format to be 'Month (full word) - Year (4 digits)' for a single event date. If the activity extends over more than a month (eg, a consultancy), the format to be 'Month (full word) – Month (full word) Year (4 digits)'
The healthcare professional's full name	Format to be 'Surname, first name middle initial' (eg, Lloyd, David M) with no other punctuation
The type of healthcare professional	To be selected from the following options (noting that no specialty for healthcare professionals will be included): • medical practitioner • pharmacist • dentist • nurse • nutritionist/dietician • optometrist • physiotherapist • psychologist • podiatrist
The healthcare professional's practice address	Details of the street number, street name, suburb or town, and state

Data element	Data Format
The type of service	A description of the service selected from the following: Advisory Board/Committee member educational meeting speaker or chair person consultant educational meeting attendee market research participant
The type of event or activity	a description selected from the following: • company meeting in Australia • company meeting overseas • independent meeting in Australia • independent meeting overseas • market research • consulting service • Advisory Board or Committee Meeting
Who the payment or transfer of value was made to	Who the payment or transfer of value was made to, selected from the following: • the healthcare professional • healthcare professional's employer • third party
The amount of the payment or transfer of value	**exclusive of GST**, subdivided into: • registration fees (where paid) • air fare and accommodation (a single amount relevant to the particular event or activity) • fees for service (a single amount relevant to the particular event or activity).

The transparency report must be sorted alphabetically by surname, then by first name, then by middle initial, then by event date. As a result, all payments and transfers of value to a particular healthcare professional will appear one after the other in chronological order for that individual.

Payments to HCPs who are employed in firms and organisations providing services to companies such as advertising agencies, PR firms, consultancies providing health economics or regulatory advice or developing submissions for companies are not required to be reported under the transparency reporting requirements. It is expected that the services they are providing to the company are not directly related to patient care.

Reasonable Expectation of disclosure of personal information – effective from 1 October 2016

In authorising Edition 18, the ACCC imposed a Condition that requires Member companies not to make payments or transfers of value unless these can be publicly reported for individual healthcare professionals. To comply with the privacy legislation, prior to accepting the payment or transfer of value the healthcare professional must be made aware that their information will be disclosed. Companies must not make a transfer of value unless they have taken appropriate steps to give notice of the disclosure obligation so that the healthcare professional would reasonably expect the disclosure.

To create the reasonable expectation of disclosure, Medicines Australia has undertaken a communications campaign with healthcare professional organisations and individual healthcare professionals. In addition, companies should inform healthcare professionals with whom they engage or contract that they will be reporting payments and transfers of value.

Prior to making a payment or transfer of value, **on each occasion** the company should give the healthcare professional a 'Collection Notice'. Companies must keep appropriate records of having given a Collection Notice to healthcare professionals to whom a payment or transfer of value is made.

This Condition became effective for activities occurring on or after 1 October 2016. Therefore, Member companies have transitioned from the (former) informed consent process to the 'reasonable expectation' process. For data collected for publication from 1 October 2016 under the reasonable expectation of publication, HCPs cannot withdraw their consent for publication as no consent was requested or given. However, there may be a need for an "aggregated data" section of the published reports to capture the payments and transfers of value relating to activities prior to 1 October 2016, where consent was not given or was later withdrawn. In future, there will no longer be the need for an "aggregated data" section of the reporting template; all data will be reported for individual HCPs.

Note that the report relating to activities between 1 May and 30 October 2016 will include BOTH payments and transfers of value made with consent and under reasonable expectations. That is, a single, combined report.

Medicines Australia has developed a model Collection Statement for companies to use to give notice to healthcare professionals so that they will reasonably expect that companies will publish the relevant information.

FIGURE 23: PROPOSED COLLECTION STATEMENT

Proposed wording to be used to give Notice to healthcare professionals of the Code's transparency obligations:

Collection Statement

(Healthcare Professional Engagement)

The Medicines Australia Code of Conduct requires your name, details of the services/activities/events ("Services") you engaged in and the amount you were paid (or the value of the benefits you received) for providing those Services to be published on [COMPANY] website for three years from the date of publication of that information by [COMPANY].

[COMPANY] collects your personal information when you are engaged by [COMPANY] to provide the Services described in the enclosed agreement.

The following personal information about you will be published on the [COMPANY] website:

- Your name and profession
- Your business/practice address
- A description of the event and service/activity you provided [COMPANY] under this service agreement
- The amount of the financial payment you received from [COMPANY] under this service agreement for this specific service/activity you provided us
- The amount of air travel, accommodation costs (room rate) and registration fee paid by [COMPANY] and/or reimbursed to you for you to attend this event or provide this service (as relevant)
- Any financial payments made to third parties as directed by you in relation to this service agreement.

[COMPANY] uses your information to facilitate the performance of the Services described above and to pay you or to provide you with a transfer of value for those Services and to give you an opportunity to check any information we hold about you before we publish that information. If you do not provide us with this information then we will not be able to engage you to perform those Services.

Our privacy policy (available at [insert website address]) includes important information about how we collect, use and disclose your personal information, how you can access or seek correction of your personal information, how you can complain about a breach of the Australian Privacy Principles and how we will deal with a complaint of that nature.

Section 41.3.3 – Validation

Section 41.3.3 requires companies to give healthcare professionals the opportunity to review and make corrections to the payment and transfer of value data collected about individual HCPs by that company. HCP data collected for publication under "reasonable expectation" will still need to be verified with each HCP as described below. Healthcare professionals must be given at least six weeks to review and verify or correct their data.

Companies must ensure compliance with the Australian privacy legislation and Privacy Principles. A healthcare professional must always be able to correct information held by a company whether published or unpublished.

Figure 24 provides a suggested model Verification Letter for companies to use when validating the data with HCPs. Using this model letter will encourage consistency between communications that a HCP may receive from different companies. However, it is not mandatory for companies to use this model letter.

The suggested model verification letter refers to providing the completed reporting template to each individual HCP with their data included. The HCP may then see their data in the form that the information will appear on the company website. Some companies may decide to provide further details relating to a specific educational event, to assist a healthcare professional to recall the event. However, these details will not be included in the published table.

The Code of Conduct does not specify the form of communication of the verification data to HCPs. It is recommended that this communication is sent by email or post; that is, a written form which provides evidence of the company's communication. It is recommended that the communication is marked as "Private and Confidential" as the communication includes the healthcare professional's personal information.

Further, it is recommended that companies request that any queries about the data are sent to the company in writing rather than provided verbally by phone.

It would also be acceptable if companies wish to make the individual HCP data available via a secure web portal. In this case the company would provide each HCP with the information required to access their data via the secure portal. The web portal could then provide information about how a HCP may query the data, such as via a query 'button'.

It is possible that a person working with a HCP could be delegated by the HCP to review their data and who might query the data on the HCP's behalf. In this case it is recommended that a company respond directly to the HCP using contact information held by the company (not the contact information provided by the delegated person if this is different) or another validated process to ensure that the response goes to the HCP.

The Code requires companies to give HCPs at least six weeks in which to raise any queries about their data. There is no requirement for companies to follow up with HCPs if they have not heard from them by the specified date. Member companies may proceed to publish a HCP's data if they have not had any response to the verification letter by the specified date.

If a HCP queries their data, it is anticipated that a company should be able to resolve the matter prior to publication date (i.e. in the four months between the close of a reporting period and the date of publication) and proceed to publish the data. In the case of HCP data that remain in dispute on the date the data is required to be published (that is, the company considers that the data is correct but the HCP does not agree), Australian Privacy Principles 13.3 and 13.4 provide the relevant requirements. The following is a suggested approach consistent with these Privacy Principles. However, companies should seek specific legal advice on these matters.

A company may proceed to publish the HCP data if the company has taken the following recommended steps:

- the HCP has been given the opportunity to review and provide any corrections to the data in accordance with the Code; and
- the company has considered the HCP's request and formed a reasonable conclusion that the HCP's data is accurate; and
- the company provides a written notice to the HCP setting out:
    - the reasons the company refuses to correct the data; and
    - the complaint mechanisms available to the HCP; and
    - advises the HCP that they have a right to request that a notation is associated with the published data stating that the HCP believes the HCP's data is inaccurate.

A company should only include a notation with the published data regarding a dispute where the HCP has requested that a notation is included with the published data. This is because the fact that a HCP has disputed the data is also the personal information of the HCP and should not be published unless the HCP consents to or reasonably expects the notation to be disclosed or reported.

It is recommended that an additional column may be included in the reporting table, to the right of the reported payments and transfers of value, in which to include such an annotation if required. The Code of Conduct does not specify including this column. Therefore it is open to companies to annotate the data, if required, in another manner.

FIGURE 24: PROPOSED VERIFICATION LETTER TEMPLATE

Proposed wording for verification letters to healthcare professionals

MODEL VERIFICATION LETTER

Dear [Name of HCP],

As a member of Medicines Australia, [Company Name] has undertaken to be open and transparent when we provide a reportable payment to a healthcare professional. Reportable payments are:

- Payments for the provision of services such as giving a lecture, chairing an educational meeting, providing advice as a member of an Advisory Board or as a Consultant
- Airfares and accommodation as part of providing those services or to attend medical education
- Conference registration fees to attend medical education

Please find attached to this [letter/email] the summary of the reportable payments that [Company Name] has provided to you for events and services occurring between 1 May 2015 and 31 October 2016 [or other relevant reporting period dates]. For events and services occurring before 1 October 2016, you have previously given your consent for [Company Name] to publicly disclose these payments. For events and services occurring from 1 October 2016 you have been notified that [Company Name] will publicly disclose these payments. [**After 31 October 2016**: You have previously been notified that [Company Name] will publicly disclose these payments.]

Your action is requested

- Please review the details of reportable payments made to you in the attached table and advise us no later than [date, at least 6 weeks after the date of receipt of the verification letter] if you wish to query any of the data.
- If we have not received any written response from you we will proceed to publish the data.

Making queries

- If you wish to query any of the data, please contact us in writing identifying the specific data that you wish to query and the basis of your query.
- Your enquiry should be directed to [contact at the company: an email address or postal address with contact person's function title].
- A [Company Name] representative will contact you to resolve the query.

Reportable payments made to you

- The attached table provides the details of reportable payments made to you, in the form in which it will be publicly disclosed.
- This includes any payments that you directed to a third party, such as to your employer.

Reporting

- The reportable payments made to healthcare professionals will be published on [date] on [Company Name] website [add the URL once the location has been established].
- The data will be publicly available for three years from the date of publication.

Further information

For further information about the Code of Conduct and transparency, please refer to the Medicines Australia website [MA URL]. Medicines Australia will provide hyperlinks from its website to all its member companies' websites where the reportable data is published.

Yours sincerely

[Company Name]
Attachment: The individual HCP's data in the form in which it will be reported [completed Table 9 of the Code Guidelines]

Publication of reports on Member Company Websites

Section 41.3 requires that each company must report on its own website the reports described under Section 41.3.1 in the following formats:

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

Companies are to provide the report on an easily accessible and easily found location on their Australian company's website, for example via a "button" or clear link from the homepage.

All reports should be publicly available by midday on the date specified in the Code. There can be no exceptions to this reporting date which is specified in the Code.

The CSV file should use a comma as the data field separator, as this is the most commonly used CSV format. If alternative field separators are used, there is the risk that the data is not easily utilisable by third parties and may require several steps to access the data in a readable form.

FIGURE 25: PROPOSED REPORTING WEBSITE WORDING

The suggested text below should appear on the page where the report has been made to assist the reader in understanding the reports and the nature of information they contain:

Website wording

As a member of Medicines Australia, [Company Name] has undertaken to be open and transparent when we provide a Reportable Payment to a healthcare professional. Reportable Payments are:

- Payments for the provision of services such as giving a lecture, chairing an educational meeting, providing advice as a member of an Advisory Board or as a Consultant
- All airfares, accommodation and/or conference registration fees provided in association with medical education or one of the services listed above.

The company has prepared the report for publication in accordance with the Medicines Australia Code of Conduct, Edition 18 and Australia's Privacy legislation. The report identifies healthcare professionals by name where their consent has been provided. Where consent has not been provided the information is reported in aggregate.

From 1 October 2016, reporting these payments will be mandatory – details will be reported because healthcare professionals should reasonably expect that all Reportable Payments will be disclosed for each healthcare professional, by name.

The report is designed to be read on this website. It is also provided as a downloadable CSV file. To comply with our privacy obligations, the report may be amended from time to time. The report here contains the most up to date information. Any use or disclosure of the data by a third party is the responsibility of that third party, who must comply with the Australian Privacy Act 1988.

For further information about the details in the report, please go to [medicinesaustralia.com.au]

The report for the period 1 October 2015 to 30 April 2016 [or other relevant reporting period dates] is available here. This report will be available for three years from the date of publication.

B. Reporting Requirements ongoing from Code Edition 17 and for the duration of Code Edition 18

Reporting of Support for Health Consumer Organisations (HCOs)

Each company must provide to Medicines Australia for publication on its website, a report listing health consumer organisations (HCOs) to which it provides financial support and/or significant direct/indirect non-financial support.

The published report must include:

- the name of the health consumer organisation, and
- 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
- 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 health consumer organisation receives.

The Reporting template is provided as Appendix 6 in the Code.

If there is a question about whether to report the sponsorship of an educational meeting in the HCO Support Report or the Third Party Meeting Sponsorship Report, companies are advised to focus on the primary purpose of the event and report accordingly. There should not be duplication of reporting. For examples of support to be included in the HCO Support Report, please refer to Table 4 of these Guidelines. Please note that despite every effort, some duplication may occur.

The HCO support report must be submitted to Medicines Australia by 30 April each year, and cover activities in the previous calendar year. That is, activities commenced on or after 1 January the preceding year or ongoing on that date through to 31 December each year. Medicines Australia will publish each company's report on its website under the Code of Conduct/Transparency Reporting page.

It is recommended that significant support for Health Consumer Organisations be based upon a written statement of agreement/contract, as suggested in the guidelines Working Together – A Guide to relationships between Health Consumer Organisations and Pharmaceutical Companies. It is the responsibility of a company to inform health consumer organisations that any support received, including monetary value, will be disclosed.

C. Reporting Sponsorship of Third Party Educational meetings and Symposia from 1 October 2015

On 1 October 2015, Educational Event reports in the form required under Code Edition 17 ceased. However, companies must continue to report sponsorships of educational meetings and symposia organised by third party organisations. The intention is that companies will continue to report sponsorships of third party meetings in a similar manner and level of disclosure as was included in educational event reports under Code Edition 17.

The template for reporting these sponsored meetings is provided as Table 7 in these Guidelines. This template is essentially the same as that found in Appendix 3 of the Code for reporting educational events, with some changes to reflect that the report now only includes third party educational meetings and symposia.

As noted in Section 41.3.5, companies are required to report sponsorships where there is a monetary transfer between the company and the third party organisation. Examples include:

- providing a lump sum sponsorship to be a gold/platinum/bronze (or similar) sponsor of the event; or
- providing a monetary payment or contribution to an institution to assist the organisation to hold a journal club meeting, grand rounds, departmental or clinic meeting; or
- purchasing a trade display space.

If a company directly provides hospitality (food and beverages), such as bringing in a plate of sandwiches and drinks or similar modest hospitality, this is not required to be reported.

If a company pays an invoice or bill (e.g. a restaurant or venue bill) on behalf of an institution or other third party organisation, this is not a reportable sponsorship. For example, if the institution arranges for hospitality to be provided by a food and beverage vendor/supplier and the company then pays the vendor/supplier, this is not a reportable sponsorship. However, such events must comply with Section 9.5 of the Code.

Sponsorship of Third Party Educational Meetings Report Timelines

Members are required to provide completed reports for sponsorships of third party educational meetings and symposia and submit the report to medicines Australia within four months after the end of the reporting period. The reports will each cover a six month period: from 1 May to 31 October, to be submitted to Medicines Australia by 28 February each year, and 1 November to 30 April, to be submitted to Medicines Australia by 31 August each year. All company reports will be published on the Medicines Australia Website within two months of receiving the reports.

TABLE 6: GUIDANCE RECOMMENDING APPROPRIATE CONDUCT FOR EDUCATIONAL EVENTS

Activity Cluster	Description (this is not exhaustive)	Education Value	Appropriate Conduct
Sponsored Activities			
Sponsored 'in institution' activities *Examples: (definitions to be added)* • Grand rounds • Journal clubs • Multi-disciplinary meetings • In-service meetings	Hospital Department or Medical Organisation provides educational content and invites the attendees. In return for sponsorship the company may provide (any, some or all of the following – this is not an exhaustive list): • trade display • short company/product presentation • attendance of company representatives to provide promotional materials to healthcare professionals.	Companies should consider the following when assessing the educational value to determine whether sponsorship is appropriate: • The primary purpose of the educational meeting must be the enhancement of medical knowledge and the Quality Use of Medicines. • The duration is usually 30 minutes to 1 hour in length. • The venue is within an institution or medical facility such as a hospital department, Area Health Service or doctor's surgery. • Company staff must be in attendance to validate that the activity took place and report the event. • Patient information discussed must be de-identified if company personnel are in attendance. Hospital policy may require company personnel to leave the meeting if any patient information is being discussed, including when the patient information is de-identified.	• Company may provide catering or a direct payment to cover the costs of hospitality based on the confirmed number of attendees. • Appropriate hospitality would be light refreshments for attendees with non-alcoholic beverages. • Sponsorship of travel or accommodation for attendees is generally not appropriate, without justification.
Sponsored Activities – Third Party educational meeting/conference			
Sole or part sponsorship of a third party educational meeting/conference	The third party organising the meeting independently determines the educational content, selects the speakers and invites the attendees.	Companies should consider the following when assessing the educational value to determine whether sponsorship is appropriate:	Acknowledgement of sponsorship must be communicated to attendees by (for example) company names appearing on invitations, brochures, banners etc or statements during educational sessions.

Activity Cluster	Description (this is not exhaustive)	Education Value	Appropriate Conduct
Examples: • Groups of GPs' educational meetings. • Area Health meetings with delegates from a range of medical practices or institutions. • Medical college or society educational meetings.	A company may propose a speaker for the educational meeting, but the final choice of speakers will be determined by the third party. If a speaker is sponsored by a company for their participation in the conference this sponsorship must be acknowledged to the audience by the speaker of the session Chairman/facilitator. The third party may acknowledge the sponsorship by allowing some or all of the following – (this list is not exhaustive): • trade display • short company/product presentation • attendance of company representatives to provide promotional materials to healthcare professionals. A formal contract or exchange of letters defining the terms of sponsorship is recommended.	• The primary purpose of the educational meeting must be the enhancement of medical knowledge and the Quality Use of Medicines. • The quality and duration of education content should justify the level of sponsorship requested. • The educational value of the event is most clearly demonstrated by a formal agenda.	If hospitality is sponsored, the same guidelines for 'company initiated educational meetings' apply (Sections 9.1 and 9.4.3). Companies must only sponsor meetings that are consistent with the Code requirements with regard to venue, hospitality, travel and accommodation etc. Venues should be consistent with the requirements outlines in the Code and Guidelines and must have the facilities to support the provision of education (eg held in a private room with audio-visual facilities). Company may provide hospitality or direct payment to cover the costs of hospitality based on the confirmed number of attendees. The hospitality provided by the company must be consistent with Section 9.4.3. Hospitality may only be provided to registered delegates at the educational meeting. Sponsorship of an educational meeting should not be paid directly to an individual healthcare professional.
Company Organised Activities			
Company organised hospitality provided to delegates attending third party educational conferences (domestic or international)	Company organised dinner for delegates attending third party conferences/congresses. • The function may include specific educational content. For example, there could be an educational speaker organised to give a presentation during the function. If educational content is not provided at the function there needs to be a clear link between the education provided at the	The educational content requirement is met by attendance at the conference. • The primary purpose of the educational meeting must be the enhancement of medical knowledge and the Quality Use of Medicines.	At international meetings, invitations typically should only be extended to Australian healthcare professionals. Companies must also be cognisant of and adhere to local Codes or regulations. Functions should only be held in venues that are consistent with the Code requirement (eg. must not be luxurious or offer extravagant hospitality; there should be no

Activity Cluster	Description (this is not exhaustive)	Education Value	Appropriate Conduct
	conference and the hospitality being provided at the function by the company.		significant focus on recreation; no entertainment should be provided). Hospitality may only be provided to attendees who are registered to attend conference sessions. If delegates arrive in the evening prior to the educational meeting for reason of the distance travelled, it is acceptable to provide a modest evening meal. Costs associated with the attendance of partners or family members must not be paid for or subsidised by the company. If there is educational content about a company's products provided at the function, only healthcare professionals may attend. The function should not detract from the main education sessions at the conference.
Company Organised Activities			
Company initiated educational meeting of short duration (less than 6 hours total education provided) *Examples*: • Educational meeting in the evening of 1 - 2 hours duration.	The company initiates and manages the agenda, speakers and invitations. • Meetings are usually held out of work hours at a location outside the workplace. • The identity of the company organising the event must be clearly communicated in all materials relevant to the event.	Companies should consider the following when constructing the educational value of the meeting: • The primary purpose of the educational meeting must be the enhancement of medical knowledge and the Quality Use of Medicines. • The educational value of the event is most clearly demonstrated by having a formal agenda, presenters who provide objective scientific/clinical educational content (NB: good quality scientific or clinical presentations from appropriate company personnel are	Educational content must be at least 1 hour in length. Venues must meet the requirements outlined in the Code and must have the facilities to support the provision of education (eg held in a private room with audio-visual facilities). Companies may provide hospitality appropriate for the time and duration of the meeting, consistent with Section 9.4.3. For evening meetings, a 2 or 3 course meal with alcoholic and non-alcoholic beverages, consistent with a normal business meeting, is appropriate.

Activity Cluster	Description (this is not exhaustive)	Education Value	Appropriate Conduct
• Half-day educational meeting. • Product launch educational meeting. • Workshop format of less than 6 hours education content.		also recognised as providing appropriate educational content), interactive discussion with attendees. • The educational program (i.e. the topics and speakers) should be reviewed and approved by internal company scientific/medical affairs function. (see also Section 9.4.1 of these Guidelines) • Invitations to the educational meeting must clearly describe the educational purpose, topic, content, meeting start and finish times and the duration of the educational sessions. • Whilst not mandatory, independent accreditation of the learning objectives for the meeting by the RACGP or similar organisation provides evidence of the educational value of the meeting.	Hospitality may only be provided based on the number of confirmed delegates. Participants must not be paid an honorarium or any other benefit in kind for their attendance (except the speaker/facilitator). In general it would not be appropriate to provide travel and/or accommodation for delegates for meetings up to 6 hours (exclusive of meal breaks) unless justified by the program structure and origin of attending delegates. No entertainment may be provided.
Company Organised Activities			
Extended company initiated educational meeting (at least 6 hours educational content) *Examples*: • Post-graduate weekends	The company initiates and manages the agenda, speakers and invites attendees. • A company controlled meeting involving a number of educational sessions. • Meetings are usually held out of work hours at a location external to the workplace. • The identity of the company organising the event must be clearly communicated in all materials relevant to the event.	Companies should consider the following when constructing the educational value of the meeting: • The primary purpose of the educational meeting must be the enhancement of medical knowledge and the Quality Use of Medicines. • Educational content must be at least 6 hours in length (face to face time, excluding breaks/meals) to justify describing the meeting as an extended company-initiated	Companies may provide hospitality appropriate for the time and duration of the meeting, consistent with Section 9.4.3. Companies should ensure that the cost of the overall conference package/per person is in proportion to the duration of the education provided. On the day of the educational meeting, a 2 or 3 course meal with alcoholic and non-alcoholic beverages is appropriate If delegates arrive in the evening prior to the educational meeting for reason of the

Activity Cluster	Description (this is not exhaustive)	Education Value	Appropriate Conduct
• Full day educational meetings • Stand-alone symposium		educational meeting ('weekend' event) and to justify the provision of accommodation to delegates. • The educational program (i.e. the topics and speakers) should be reviewed and approved by internal company scientific/medical affairs function. (see also Section 9.4.1 of these Guidelines) • Invitations to the educational meeting must clearly describe the educational purpose, topic, content, meeting start and finish times and the duration of educational sessions. • Whilst not mandatory, independent accreditation of the learning objectives for the meeting by the RACGP or similar organisation provides evidence of the educational value of the meeting.	distance travelled, it is acceptable to provide a modest evening meal. Hospitality may be provided based on the number of confirmed delegates. Travel must meet the requirements outlined in the Code. Meeting location should be selected to be convenient for delegates so that excessive travel and accommodation is not required. In general travel and/or accommodation for delegates should only be provided if justified by reason of the program structure and the origin of the attending delegates. Accommodation should only be provided if the distance travelled by delegates to attend the meeting justifies it and the meeting is > 6 hours for one night and > 9 hours (face to face time) for two nights. Accommodation should generally not be provided for delegates residing in the city/town where the meeting is held. Participants must not be paid an honorarium or any other benefit in kind for their attendance (except speakers or facilitators). Companies must not subsidise or pay for the attendance of partners or family members of healthcare professionals. Venues must meet the requirements outlined in the MA Code.

Activity Cluster	Description (this is not exhaustive)	Education Value	Appropriate Conduct
Company Organised Activities			
Company initiated educational meeting with Program content and speakers developed by independent Steering Committee	The Steering Committee of recognised independent experts determines the educational program content and selects the speakers. The company may propose a speaker for the educational meeting to the Steering Committee, but the final selection of speakers will be determined by the Steering Committee. See also Section 9.4.1 of these Guidelines.	• Companies should consider the following when facilitating the development of the meeting: • The primary purpose of the educational meeting must be the enhancement of medical knowledge and the Quality Use of Medicines. • The educational value of the event is most clearly demonstrated by having a formal agenda. • The Steering Committee's decisions on content and speakers are final. • Invitations to the educational meeting must clearly describe the educational purpose, topic, content, meeting start and finish times and the duration of the educational sessions. • Whilst not mandatory, independent accreditation of the learning objectives for the meeting by the RACGP or similar organisation provides evidence of the educational value of the meeting.	Conduct the same as company initiated educational meetings according to duration (short or extended as applicable) as described above in this table.

FIGURE 26: REPORTING PAYMENTS TO HEALTHCARE PROFESSIONALS UNDER REASONABLE EXPECTATIONS FROM 1 OCTOBER 2016 (SECTION 41.3)

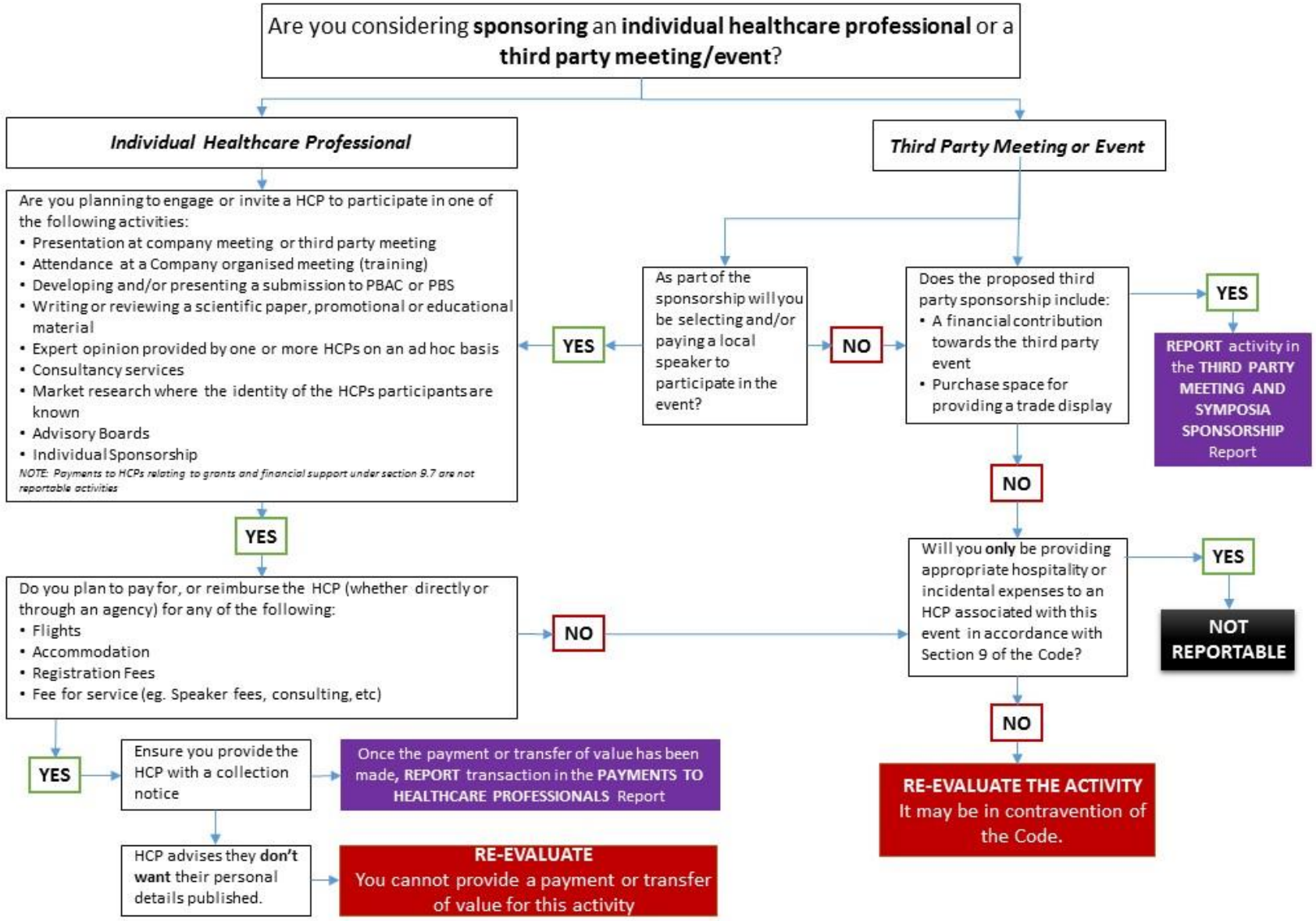


TABLE 7: REPORTING TABLE FOR SPONSORSHIP OF THIRD PARTY MEETINGS AND SYMPOSIA

from 1 October 2015 (Section 41.3.5)

Reporting Period (For example, October 2015 - April 2016)

Company Name:

Number of events sponsored:

Description of Third Party Meeting or Symposium including duration of educational content delivered	**Venue**	**Professional status of attendees**	**Purpose of financial support provided**	**Total cost of any hospitality, travel, accommodation, registration fees sponsored**	**No. of attendees**	**Total cost of sponsorship contribution**
Companies to provide as much information as they feel necessary to explain the educational purpose For example: • Title of event/symposia • Name of organisation that organised the event • Duration of educational component (hours of education)	Specify: • Venue name • Location (town/city and state/territory)	Specify: For example: • Anaesthetists • General Practitioners • Nurses • Pharmacists	Specify: • If the sponsorship specifically supported any of the following elements: • Hospitality (food and/or beverages) • Travel expenses • Accommodation • Event registration fees	$ cost This must state the total cost of the elements sponsored as described in the "Purpose of financial support provided" column. A breakdown of those costs may be provided if desired.	XX	$ Total cost of sponsorship: comprises the costs stated in column 5 plus any other costs, including where applicable: • Trade display space • Venue hire • Any speaker fees, chairperson fees, or faculty remuneration (where these are not reported for individual HCPs; e.g. for an international speaker/chairperson) • Transportation costs (travel expenses from column 5 and any other transportation costs) • Third party costs such as event organiser • Audio visual costs

TABLE 8: EXAMPLE OF A COMPLETED THIRD PARTY SPONSORSHIP REPORT

(For reporting sponsorships of third party events from 1 October 2015)

Summary of Events sponsored by Pharmamed: Reporting Period October 2015 – April 2016

Company Name: **Pharmamed Pharmaceuticals**

Total number of events held: **12**

Description of Third Party Meeting or Symposium including duration of educational content delivered	Venue	Professional status of attendees	Purpose of financial support provided	Total cost of any hospitality, travel, accommodation sponsored	Number of attendees	Total cost of sponsorship contribution
April – 3 events						
Sponsor of Melbourne Oncologic Diseases Group (MODG) Meeting, providing updates from recent international scientific conferences and case reports from public hospitals and private clinics. 7 hours educational content.	St Vincent's Private Hospital, Melbourne, Victoria	Oncologists, Radiologists, Nurses, Pharmacists, Registrars	Sponsorship Only	N/A	50	$3,500
June – 2 events						
Journal Club Infection Control Literature Review	St Vincent's Hospital, Sydney	Virologists	Fruit & sandwich lunch; non-alcoholic beverages provided	$300	25	$300

Description of Third Party Meeting or Symposium including duration of educational content delivered	Venue	Professional status of attendees	Purpose of financial support provided	Total cost of any hospitality, travel, accommodation sponsored	Number of attendees	Total cost of sponsorship contribution
Psychiatry Ground Rounds Forensics and Court Liaison	Prince Alfred Hospital, Melbourne	Psychiatrists	Fruit & sandwich lunch; non-alcoholic beverages provided	$150	10	$150
July – 2 events						
Pharmamed sponsored the 9th Annual Breast Cancer Nurses Conference This event was organised by the Cancer Nurses Conference Organising Committee and Pharmamed was not responsible for inviting the attendees or organising the educational content, the hospitality, accommodation or travel. 2 days – 15 hours education	Melbourne Convention Centre	Oncology nurses	N/A	N/A	104	$20,000

TABLE 9: REPORTING TEMPLATE FOR PAYMENTS AND TRANSFERS OF VALUE TO HEALTHCARE PROFESSIONALS

HCP Payments and Transfer of Value (ToV) Report for the period 1 October 2015 to 30 April 2016 [or other dates consistent with reporting schedule]

Company Name: ABCD Limited

Date of event or provision of service	**Full name of HCP**	**Type of HCP**	**Practice Address**	**Type of Service**	**Type of Event or Activity**	**Payment or Transfer of value made to:**	**Registration Fees**	**Air Travel & Accommodation costs**	**Fees for Service and Consultancy**
November-2015 November 2015 – April 2016	Lloyd, David M	Medical Practitioner Pharmacist Nurse Psychologist Optometrist Nutritionist/ dietician Physiotherapist Dentist Podiatrist	No / Street / Suburb or Town / State	Advisory Board/ Committee member Educational meeting speaker or chair person Consultant Educational meeting attendee Market research participant	Company meeting in Australia Company meeting overseas Independent meeting in Australia Independent meeting overseas Market Research Consulting Service Advisory Board or Committee Meeting	Health Care Professional Health Care Professional's Employer Third Party	$	$	$
Aggregate total of ToVs where HCPs have not consented to data being reported individually									
Aggregate value of payments and ToVs							$	$	$
Aggregate number of HCPs who did not consent to one or more payment or Transfer of Value [A single number representing the total number of HCPs who did not give consent]				#					

NOTE: An additional column may be included, to the right of the “Fees for Service and Consultancy” column, if required, to annotate that data is in dispute with a HCP. However, this column is not necessary if no annotation is required for any data.

TABLE 10: REPORTING OF PAYMENTS AND TRANSFERS OF VALUE TO HEALTHCARE PROFESSIONALS – FREQUENTLY ASKED QUESTIONS

HOW TO REPORT	
What is the date that is reported in the report table? Is it the date of payment or the date that the transfer of value is made?	The date in the report template is the date of the event or activity or the provision of service (refer to the dot points in Code Section 41.3.1, bottom of page 71). It is NOT the date that you paid the healthcare professional, or the date that the HCP takes the flight to attend the educational meeting. However a company cannot report a payment or a transfer of value until the payment/transfer is made to the HCP. For example, if a company supports a HCP to attend an educational meeting where they are also giving a presentation for which the HCP is paid an honorarium for their time to prepare the presentation and deliver it. In this case there may be an airfare, accommodation and the honorarium for giving the presentation. The airfare and accommodation would be paid for by the company (perhaps in advance of the event) and the honorarium would be paid on receipt of an invoice from the HCP. The payment and transfers of value would be reported in the relevant six-month report using the date on which the educational event occurred. However, if the HCP is delayed in submitting the invoice for the honorarium, this cannot be reported until the honorarium has actually been paid. If the payment of the honorarium does not occur until the next (or a subsequent) reporting period, the payment would be included in the next report using the date of the event, NOT the date the honorarium was paid. Therefore, there may be payments and transfers of value relating to one event that are reported in two or more six-monthly reports. Nevertheless, the date appearing in each report is always the date of the event. Further, each payment or transfer of value is only included in a report once. For invoices received or paid after 1 October 2016 that relate to activities occurring on or before 30 September 2016, which would have occurred whist the opportunity to consent was in effect, these payments would be reported in the same manner in the report table. That is, if the HCP consented to the reporting, it would be reported individually. If the HCP did not consent it would be reported in aggregate. If an airfare or accommodation is paid for in advance, these cannot be reported until the event has occurred and the HCP has used the airfare and accommodation. The HCP might not be able to attend the event (for example due to illness), in which case the transfer of value has not been made to the HCP and cannot be reported.
Are fees associated with booking an airfare or changing a flight included in the amount reported?	Yes, the amount reported is the amount the company paid for the airline ticket, including any booking change fees. The principles here are consistency of reporting, without selecting certain fees to be included/excluded, and to report the amount that the HCP would have paid if they made the air travel booking themselves. For example, airlines might charge additional fees for airport taxes, fuel taxes, a booking fee, a change of schedule fee etc. In addition, the cost of a flight might be higher if it is changed after the initial booking. All of these costs incurred by the company in providing the airfare to the HCP should be reported.

	If a company employs a travel agent to make airline bookings for HCPs, and a fee is paid to the travel agent, the travel agency fees do not need to be reported for each HCP. The travel agency costs are a business cost, which a HCP would not incur if they made the airline booking themselves.
When sponsoring Third Party educational meetings, the sponsorship packages often include complimentary event registration fees. If a company passes on a complimentary registration to a HCP, is that a reportable registration fee?	Yes, the registration should be reported for the individual HCP. The HCP is receiving from the company the value of the conference registration, which the HCP would otherwise have to pay for themselves. The company would report the amount of the conference registration paid by other conference attendees. It would be good practice for the company to retain documentation to demonstrate the cost of conference registration, such as a registration form. In principle, this would apply to any complementary air fares, accommodation or registration fees that are transferred to a healthcare professional.
How should companies report payments and/or transfers of value that relate to a couple or several activities? For example, one contract with a HCP might include being a steering committee member as well as being a speaker at a meeting. This relates to the situation where there is a single payment for all the activities and where there are separate payments made for each activity.	The reporting table was originally designed so that companies could pick one selection from a list to describe the type of service and the type of activity or event. We now realise that this is not always going to be the case. Therefore, companies may choose two or more different selections that apply to a single event or activity. It is up to companies to determine the best way to report a particular event, keeping in mind that the primary audience for the report are Australian patients. The more the payment and transfer of value information is broken down into discrete activities, it is more likely to be easily understood. That is, each line in the report would relate to one activity within a group or series of activities. In some cases it might not be possible to attribute payments and transfers of value to one activity within a group of activities (for example, an airfare and accommodation might relate to several activities relating to an educational meeting, occurring together). In this case, a company should choose the description of the type of service and type of event or activity that best describes the activity.
A healthcare professional receives some transfers of value themselves (e.g. an airfare and accommodation) and directs that an honorarium should be paid to a third party (such as into their research fund). How should this be reported?	This question will only relate to monetary payments. A registration fee or air travel and accommodation can only be received by the healthcare professional who has participated in the activity. Note that if a company pays a registration fee to a conference organiser for an attending HCP, this is a transfer of value to the attending HCP (not 'a third party'). If, for one event or activity, there are transfers of value to the HCP and a payment made to a third party or the HCP's employer, this could be indicated in the reporting table by indicating both "healthcare professional" and "Third Party" in the 'Payment made to:' column in the table. The relevant transfers of value and payments could then be placed in line with each term. See Example A below.

Example A:

Date of event or provision of service	Full name of HCP	Type of HCP	Practice Address	Type of Service	Type of Event or Activity	Payment made to:	Registration Fees	Travel & Accommodation costs	Fees for Service and Consultancy
November-2015	Lloyd, David M	Medical Practitioner	51 High Street, Anytown, NSW	Educational meeting speaker or chair person	Independent meeting in Australia	Health Care Professional Third Party		$1507.00	 $2200

HOW TO REPORT (continued)	
How would a consultancy activity be reported where the consultancy covers activities/services both before 1 October 2015 and post-1 October 2015, and the payment is made after 1 October 2015?	In the interest of transparency, generally if the payment to the HCP is made after 1 October 2015, a company would report the whole consulting project because it was ongoing after 1 October 2015. If the consulting activity is ongoing after 1 October 2015, but some payments were made before 1 October 2015 for work completed before 30 September 2015, it would also be reasonable to only report the activity and related payments made after 1 October 2015. There is also the matter of consent for reporting the payments and any transfers of value. When the consultancy was arranged prior to 1 October 2015, consent might not have been obtained for reporting the payments and transfers of value occurring after 1 October 2015 but before 1 October 2016. In this case, a company should seek consent from the HCP for reporting the payments and transfers of value. This could be done as an addendum to the consultancy contract. For invoices received or paid after 1 October 2016 that relate to activities occurring on or before 30 September 2016, which would have occurred whist the opportunity to consent was in effect, these payments would be reported in the same manner in the report table. That is, if the HCP consented to the reporting, it would be reported individually. If the HCP did not consent it would be reported in aggregate.
If a HCP is engaged to provide services before 1 October 2016 and these services will continue after 1 Oct 2016, does this require a new contract to be signed with the HCP, which would exclude the request for consent to publish the reportable payments?	This question may require companies to obtain legal advice. The principle is that for activities occurring after 1 October 2016, all payments and transfers of value must be reported. One approach could be to renew the contract with the HCP for activities occurring after 1 October 2016. In the revised contract the consent clause would be amended to remove reference to consent to publish reportable payments and a collection statement would be given separately to the HCP. However, companies should seek formal advice on any amendments required to their contracts with healthcare professionals to ensure compliance with Section 41.3.2 of the Code after 1 October 2016.

HOW TO REPORT (continued)	
If a company's global headquarters or another country affiliate provides a payment or transfer of value to an Australian HCP, is that reportable under the Medicines Australia Code?	The Medicines Australia Code, with respect to the transparency reporting requirements, only applies to Medicines Australia's Members. Therefore, Medicines Australia is not able to require a company in another country to report a payment or transfer of value. If an overseas affiliate or HQ pays for an Australian HCP to engage in activity, or supports the HCP's attendance at an educational meeting and then bills the Australian affiliate that is a Medicines Australia member, the payment and/or transfer of value should be reported. Similarly, if the Australian affiliate passes on the costs/payments to its overseas affiliate or HQ, this means that the Australian member company is not, in effect, making the payment or transfer of value. This would not be reportable. However, it would not be consistent with the principle of transparency for this to be a regular practice, particularly if the service is provided to the Australian affiliate or the engagement with the HCP is primarily by the Australian affiliate. These arrangements should not be made in order to avoid transparency of payments and transfers of value to Australian HCPs.
Are payments or transfers of value to HCPs from another country reportable under the Medicines Australia Code?	No, payments to HCPs from another country who are not caring for Australian patients are not reportable – for example, a US-based HCP is brought to Australia to give a **series** of educational presentations. The principle underpinning transparency is to provide transparency for Australian patients about how the HCPs who care for them interact with pharmaceutical companies.
If breakfast is included in the room rate for accommodation, what value for the accommodation should be reported?	Companies should report the cost of the room as paid to the hotel although breakfast was included. Companies should not deduct an amount equivalent to a breakfast when reporting the accommodation. However, if breakfast is charged for in addition to the room rate, companies would only report the room cost and NOT the breakfast cost. Note that these costs are exclusive of GST.

DISPUTES ABOUT DATA ACCURACY	
If a HCP disputes one or more amounts to be reported for them, should the data be published before the dispute is resolved? Should the data be included in the "aggregate reporting" section of the reporting table until the dispute is resolved?	The Code (Section 41.3.3) requires that companies provide HCPs with the opportunity to review information about payments and transfers of value to be reported for each HCP. This applies to BOTH working with informed consent and with the reasonable expectation of publication. This validation must be completed prior to publication date. It is most likely that this validation will be conducted during the four months between the end of the reporting period and the publication date. It is also acceptable to undertake validation in "real time" immediately after the conclusion of the activity or after the transfer of value has taken place. Hopefully, most HCPs' questions or disputes about the data would be able to be resolved prior to publication. However, if a dispute about the data is not resolved prior to the publication date, the following approach is recommended: <u>For activities between 1 October 2015 and 30 September 2016 (informed consent)</u> It is anticipated that if a HCP has disputed the accuracy of the data for publication, effectively the HCP's consent to publication would also be withdrawn. Therefore, the data would be included in the "aggregate" section of the table, along with the data for HCPs who have not given consent for their data to be published. Alternatively, if the HCP has clearly <u>not</u> withdrawn their consent to publication, the data could be published with an indication (e.g. an asterisk and a few words such as "under dispute") that the data has been disputed. Once the query on the data has been resolved, the correct data would be published in the table and the indicator of dispute deleted. <u>For activities after 1 October 2016</u> If a HCP queries their data, it is anticipated that a company should be able to resolve the matter prior to publication date (i.e. in the four months between the close of a reporting period and the date of publication) and proceed to publish the data. In the case of HCP data that remain in dispute on the date the data is required to be published (that is, the company considers that the data is correct but the HCP does not agree), Australian Privacy Principles 13.3 and 13.4 provide the relevant requirements. The following is a suggested approach consistent with these Privacy Principles. However, companies should seek specific legal advice on these matters. A company may proceed to publish the HCP data if the company has taken the following recommended steps: • the HCP has been given the opportunity to review and provide any corrections to the data in accordance with the Code; and • the company has considered the HCP's request and formed a reasonable conclusion that the HCP's data is accurate; and • the company provides a written notice to the HCP setting out:

	○ the reasons the company refuses to correct the data; and ○ the complaint mechanisms available to the HCP; and ○ advises the HCP that they have a right to request that a notation is associated with the published data stating that the HCP believes the HCP's data is inaccurate. A company should only include a notation with the published data regarding a dispute where the HCP has requested that a notation is included with the published data. This is because the fact that a HCP has disputed the data is also the personal information of the HCP and should not be published unless the HCP consents to or reasonably expects the notation to be disclosed or reported. Australian Privacy Principle 13 (APP 13) requires that a company (such as a pharmaceutical company) must correct 'incorrect personal information' it holds. The information collected about a HCP for reporting payments and transfers of value is personal information. Therefore, if at any time a HCP questions the information that a company holds and/or it has published about them and it is discovered that the information is incorrect, the company must correct the information.
If a HCP questions the accuracy of data reported about them once the data has been published, should the individual HCP's data be removed from the public report and included in the aggregate section of the report template until the dispute is resolved?	<u>A. Informed consent (activities occurring between 1 October 2015 – 30 September 2016)</u> If a HCP has consented for the data about payments and transfers of value to them to be published, and the data has been published, a HCP cannot withdraw their consent "retrospectively". If a HCP withdraws consent for publication, this relates to all activities and related data that has not at that time been published. That is, the lack of consent would apply <u>prospectively</u> from the date the withdrawal of consent is communicated to the company. Thus, if consent is withdrawn before the data is published, the relevant HCP's data would be included in the aggregate section of the reporting template, not reported individually. Note that consent to publish the information is given on a company by company basis. It follows that any withdrawal of consent will be on a company by company basis. Australian Privacy Principle 13 (APP 13) requires that a company (such as a pharmaceutical company) must correct 'incorrect personal information' it holds. The information collected about a HCP for reporting payments and transfers of value is personal information. Therefore, if at any time a HCP questions the information that a company holds and/or it has published about them and it is discovered that the information is incorrect, the company must correct the information. Note that this is a separate matter to the withdrawal of consent for publication of personal information – see the preceding paragraph that relates to withdrawal of consent. <u>B. Reasonable Expectations of publication (activities occurring after 1 October 2016)</u> When working with the reasonable expectation of reporting a HCP's receipt of payments or transfers of value, the question of withdrawal of consent will not apply. By receiving the payment or transfer of value, and a collection notice as described in the Code Guidelines, the HCP should expect that the information will

	be published. There is therefore no ability for a HCP to withdraw consent, because consent has not been requested or given. Note, that the requirement for correction of incorrect personal information under APP 13 (see above) does apply. For activities occurring after 1 October 2016, data will no longer be reported in aggregate, because all payments and transfers of value must be reported. However, there may be a need for an "aggregated data" section of the published reports to capture the payments and transfers of value relating to activities prior to 1 October 2016, where consent was not given or was later withdrawn. In future, there will no longer be the need for an "aggregate" section of the reporting template; all data will be reported for individual HCPs. Note that the report relating to activities between 1 May and 30 October 2016 will include BOTH payments and transfers of value made with consent and under reasonable expectations. That is, a single, combined report.
THIRD PARTY EDUCATIONAL MEETINGS & REPORTABLE PAYMENTS	
If a company is involved in supporting an educational meeting arranged by a third party (such as a medical or nursing college), which includes the provision of: • a payment to a HCP for giving a presentation or airfares, and/or • accommodation, and/or • registration fees for some attendees, Which of these payments and/or transfers of value would reportable for the individual HCPs?	The principle underpinning reporting payments and transfers of value made to HCPs is to provide transparency where there is a potential that the provision of a payment or transfer of value from a company might influence the HCP. It follows that if a company is not involved in making a payment/transfer of value to a particular HCP, there is minimal or no risk of influence. If a company sponsors a third party educational meeting and the company indicates which attendees should receive payment for their registration; or the company determines or recommends which HCPs should be selected as speakers/chairpersons, and the company's sponsorship is used to provide payments or transfers of value to these HCPs, the payments and transfers of value would need to be reported. On the other hand, if the company does not determine or recommend which HCPs should receive a registration fee; or does not determine or recommend HCPs as speakers/chairpersons etc – these are wholly determined by the third party organisation – any payments or transfers of value to HCPs would not be reportable. It is also not reportable if for some reason the company is advised which HCPs received the support to attend the educational meeting, the rationale being that the company did not provide the support directly to the HCPs and the transfer of value was not made indirectly through a third party on the company's behalf. The transfers of value are made independently of the company. This is also analogous to when payment for participation in market research is reportable; such payments are only reportable when the company determines which particular HCPs the market research is conducted with and therefore knows the identity of the HCPs to whom a payment is made.

Are payments to HCPs for company supported medical practice activities reportable payments?	Company supported Medical Practice Activities (Code Section 9.10), where a service is provided to medical practices and/or patients, are not reportable payments. For example, if a company contracts a third party to employ diabetes nurse educators and these nurse educators attend a number of general practices to provide education to diabetic patients, the payments to employ the nurse educators (essentially the nurses' salaries) are not reportable payments.
REPORTING DIFFERENT TYPES OF ACTIVITIES	
A company is a sponsor of a third party educational meeting. At the meeting there is a scientifically-based competition, such as a poster competition, where there is a prize of a grant to enable a HCP to travel to attend another educational meeting. The selection of the winner of the prize is wholly independent of the sponsoring company (for example, by a scientific steering committee). Is this a reportable payment?	As the award of the prize is wholly independent of the sponsoring company, there is no relationship between the company and the winning HCP. Therefore, the prize is not a reportable payment or transfer of value. The company is not providing any air travel, accommodation or conference registration fee directly to the HCP. If, however, the company was involved in, for example, booking the airfare/accommodation or paying the registration fee for the HCP, this closer involvement would require the transfer of value to be reported. The sponsorship of the meeting would be reported in the Third Party Meetings and Symposia Sponsorships Report. If the same scenario is applied to a company-organised educational event, there can be no prize or educational grant provided to a HCP as part of a poster competition or similar. This would be contrary to Code Section 2.7 which prohibits competitions where there is a prize offered by a company.
REPORTING DIFFERENT TYPES OF ACTIVITIES (CONT)	
If a company provides a fee to a HCP for being an expert witness before the Courts, is that a reportable payment?	The Australian Medical Association (AMA) published a Position Statement in 2013 outlining the ethical guidelines for a medical practitioner who is called as a medical witness to give evidence in court, at a tribunal, or as part of an alternative dispute resolution process. The Guidelines state that when acting as a medical witness, the role of the medical practitioner is to provide impartial evidence to assist the court in reaching a decision. It is not the role of the medical practitioner to act for a party. Further, payments to doctors for providing expert witness to the courts in the US is not a reportable payment under the US Sunshine Act requirements. It is therefore reasonable that any payments to an Australian HCP for providing expert witness to the Courts would not be required to be reported under the Medicines Australia Code of Conduct transparency provisions.

[3] Australian Medical Association. *Ethical Guidelines for Doctors Acting as Medical Witnesses.* Canberra 2011

If a company provides a fee to a HCP for providing an expert opinion for inclusion in a regulatory submission or in relation to a Code of Conduct complaint, is that a reportable payment?	Yes, that is a reportable payment. The HCP is providing a consulting service to the company, for which all payments and transfers of value are reportable.
If a company engages or contracts a HCP to provide a service that is unrelated to their practice as a HCP, is the payment and any transfers of value (e.g. flights) reportable? An example is where a HCP is a patient, who is provided with flights and accommodation to give a presentation about their experience as a patient; the fact that they are a HCP is unrelated to their engagement as a patient speaker.	If a practising HCP receives a payment of Transfer of Value it should be reported. Examples of non-practising HCPs are medical practitioners, pharmacists or nurses who are journalists or media identities who do not care for patients as a health professional. In the example of a practising HCP who gives a presentation about their experience as a patient, and receives a payment, this would be reportable.
CONSISTENCY OF REPORTING	
Are companies required to develop 'methodology' statements that describe their methodology for reporting payments and transfers of value, similar to the UK and US?	No, there is no requirement in the Medicines Australia Code for companies to prepare methodological notes. By providing guidance in the Code of Conduct Guidelines, and in these FAQs, we intend to promote consistency of approach between companies.
What information will be included on companies' websites and Medicines Australia's website to explain how the data has been collated; what's included; what's not included; how the information should be interpreted? This relates to both patients as well as HCPs.	When the HCPs' data are published, Medicines Australia will provide recommended text for companies to use on their websites to explain how the reportable payments and transfers of value should be interpreted. This will provide context for the reported information. This is to promote consistency for consumers if they visit several member companies' websites. However, companies may, of course, provide additional or different information if they choose. The information prepared by Medicines Australia will include a glossary of terms; for example to explain what is an Advisory Board, or what consulting services a HCP might provide to companies; or what is meant by payment to a 'third party'. Medicines Australia will also prepare recommended wording for sending the data to HCPs for validation. This will be available in early 2016.
OTHER QUESTIONS	
If a HCP decides to repay or refund the company after receiving a payment or transfer of value, how would the reporting of this be handled – both before it has been publicly reported and once it has been reported?	This is an unusual scenario, which you would not expect to see very often. However, this is Medicines Australia's recommended approach:

	A. If the payment has not been reported If the payment has not been publicly reported, the HCP's data should be removed from the report to be published. Note, reportable payments and transfers of value include both monetary payments and transfers of value (airfare, accommodation, registration fees). If a HCP only 'repays' the monetary payment, but has also received an airfare and accommodation (which are not repaid), the airfare and accommodation must still be reported. In this (unusual) scenario, it would be worthwhile checking that the HCP still consents to reporting of transfers of value that have not been repaid (if this occurs between 1 October 2015 and 30 September 2016, when informed consent applies). After 1 October 2016, a company is required to report all payments and transfers of value. Therefore, any transfer of value that has not been repaid would still be required to be reported. B. After the payment has been publicly reported Australian Privacy Principle 13 (APP 13) requires that a company (such as a pharmaceutical company) must correct 'incorrect personal information' it holds. The information collected about a HCP for reporting payments and transfers of value is personal information. It follows that if a HCP repays a payment for a service or refunds to a company the cost of an airfare/accommodation/registration fee, the information that was previously published relating to these reportable payments would no longer be correct. Therefore, a company should correct the previously published information to either remove it from the report (if wholly repaid/refunded) or adjusted to reflect the refunded payments or transfers of value (if partly repaid/refunded).

Code Administration

Complainants and subject companies are encouraged to review the Guidance Notes on lodging and responding to a complaint that can be found on the Medicines Australia website at:

http://medicinesaustralia.com.au/code-of-conduct/lodging-responding-to-a-code-of-conduct-complaint/

Members of the Code Secretariat are available to provide advice 'without prejudice' to member and non-member companies and all stakeholders. When advice is characterised as being 'without prejudice,' neither a complainant nor a subject company is permitted to refer to the advice in the complaints process before the Code or Appeals Committees unless it is to provide evidence of an agreement previously concluded by the parties.

A summary of the complaints and appeals process is provided in Figure 24 in these Guidelines.

Record Keeping

Pharmaceutical companies should ensure that internal procedural documents include a requirement to track the approval and distribution process for all promotional material. Companies should keep a record of communications to agencies notifying them of the completion of a campaign, the expiry or approval for a particular item or advertisement and the withdrawal of material found in breach of the Code by the Code of Conduct Committee.

If a complaint is lodged relating to the continued use of materials required to have been withdrawn, the Committee will not accept a company response that uses poor record keeping as a reason for not withdrawing all materials found to be in breach, or for the inadvertent placement of an old advertisement by a contracted advertising agency, which does not comply with the current requirement of the Code.

Companies should also maintain records in relation to sponsorships or contracts with third parties.

Acceptance of Complaints

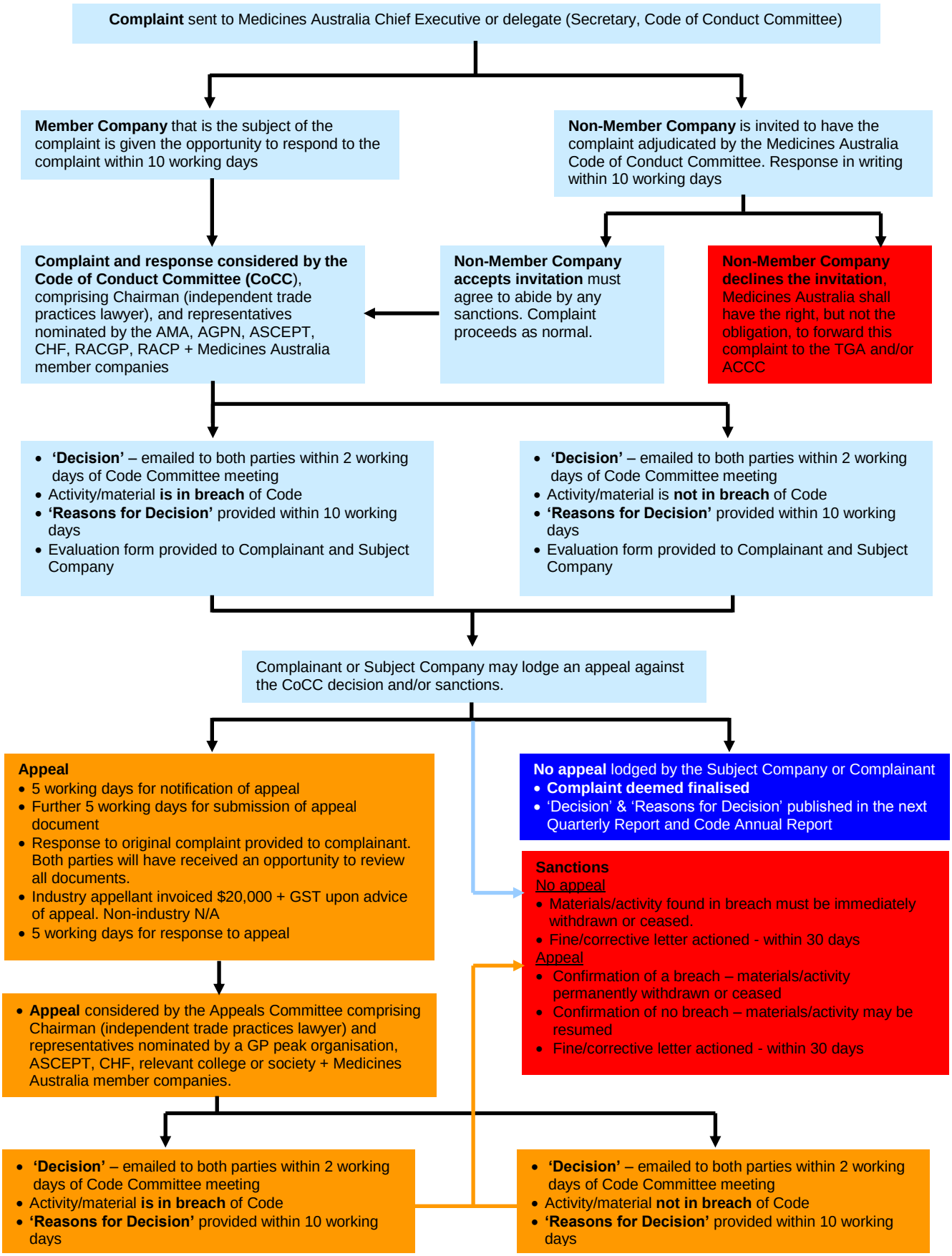
Section 20.1 of the Code provides the Secretariat with the discretion to either not accept a complaint, or accept and delay referring the complaint to the Code Committee if substantially the same subject matter (e.g. a claim or advertisement for the same product) is subject to legal proceedings between the same parties (complainant and subject company) in an Australian court or Administrative Tribunal.

Double jeopardy

Section 20.1 also provides the secretariat with the discretion to not accept a complaint if the subject matter has already been substantially dealt with by the Code Committee. That is, the Secretariat has the discretion to not accept a complaint under a particular section or sections of the Code in relation to the same activity or same material irrespective of whether there was a finding of a breach of the Code. In these circumstances the complainant will be referred to the outcome of the previous complaint.

If a complaint is received alleging a breach of a different section of the Code than previously considered, or in relation to revised materials, this will be considered to be a new complaint. Similarly, if it is alleged that the material or activity found in breach of the Code has not been withdrawn or the activity has not ceased, this will be considered to be a new complaint.

FIGURE 27: COMPLAINTS AND APPEALS PROCESS SUMMARY



Section 27 Abuse of the Code

The purpose of this section of the Code is to ensure that every opportunity is given to the Code of Conduct Committee to consider valid and meaningful complaints by reducing the possibility of having to consider trivial or vexatious complaints.

To sustain an allegation that a single complaint is in breach of this section, the company that is the subject of the complaint would need to demonstrate concerns such as:

- the sole matter subject of the complaint is trivial
- the matter could have been successfully dealt with via further intercompany dialogue pursuant to the Intercompany Dialogue Guidelines in Appendix 1 of the Code
- there was no patient safety issue involved in the complaint
- the complaint involved only a competitive issue
- that even though a non-technical breach was found, the sanction imposed by the Committee did not go beyond what the respondent company had already undertaken in the course of intercompany dialogue, or
- that even though it might be a technical breach of the Code (for example, type size not complied with) it was not appropriate to bring this individual trivial matter to the Code of Conduct Committee when it could easily have been resolved by intercompany dialogue (see above).

A series of complaints against either a single company or a number of companies may breach this section for similar reasons to those raised above.

It is important for companies to understand that a finding of an abuse of the Code is not dependent upon whether a breach of the Code is found or not. Rather, it is about using the Code in an inappropriately trivial way that would preclude the Code or Appeals Committee's consideration of other more meaningful complaints.

For illustrative examples of complaints where an allegation of Abuse of the Code under the relevant Code Section (Section 12.3 in Edition 15; Section 23 in Edition 16; Section 25 in Edition 17) has been raised, please review the following:

- Complaint Clopidogrel (954) (Code of Conduct Annual Report 2008-2009)
- Complaint Tysabri (1041) (Code of Conduct Annual Report 2009-2010)
- Complaint Sevikar Sales Aid (1076) (Code of Conduct Annual Report 2011-2012)
- Complaint Novartis Representative Conduct (1104) (Code of Conduct Annual Report 2013-2014)

The Code Committee may, having considered a number of competitive inter-company complaints, ask that a mediation meeting be held with those two companies. During this mediation phase an agreement would be sought from the two companies that no further complaints be lodged until the finalisation of the mediation process. This mediation process has been successful in the past and will be recommended by the Code Committee should it consider that resolution between two companies may be achieved by such discussions.

Section 28 Sanctions

Guidelines for determining Code Sanctions

The purpose of this section is to provide information on the general principles and factors the Code of Conduct and Appeals Committees take into account when considering and determining sanctions under the Code.

This section also serves to assist the Code of Conduct and Appeals Committees to achieve consistency in their decision making when imposing sanctions. It will also assist complainants and subject companies in understanding the factors that may be considered by the Code and Appeals Committees when determining sanctions.

These guidelines do not alter the Code of Conduct and Appeals Committees' obligation to have regard to all relevant circumstances and factors in any individual complaint before them.

Definition of Sanction

In the context of the Code a sanction is imposed on a company in response to having been found to have breached the Code. The three main types of sanction are:

- to cease the activity and withdraw the materials found in breach (the minimum sanction); and/or
- to issue a corrective letter or advertisement; and/or
- to pay a monetary fine.

Purpose of Sanctions

Sanctions are intended to ensure that information provided by companies is in the interest of promoting quality use of medicines and protecting public health and safety.

A high level of compliance with the Code demonstrates the industry maintains high standards when engaged in the marketing and promotion of its products and conducts itself responsibly in self-regulation of these activities.

The specific purposes of sanctions are to:

- encourage compliance with the Code;
- ensure that any materials found in breach are not used again or any activity found in breach is ceased; and
- ensure that false or misleading information is corrected.

A sanction is a deterrent to the company found in breach of the Code but also provides information to all companies to assist in complying with the Code.

Corrective letter and advertisement procedures

- In the case of a corrective letter the Code Committee will specify to whom the letter must be sent. This will reflect the audience who may have received the material found in breach of the Code.
- Where the sanction includes a corrective advertisement the placement must be in the same publication in which subject material was original placed. The corrective advertisement must be of the same size and prominence as the original advertisement. (Section 28.2 of the Code)
- Corrective action (prepared and published or distributed) must be completed within 30 calendar days from receipt of the Reasons for Decision of the Code of Conduct or, in the case of an appeal, Appeals Committee.
- A copy of the distributed corrective letter (on company letterhead bearing the signature of the company Managing Director or Medical Director) or published corrective advertisement should be provided to Medicines Australia for the complaint records.
- A retraction statement must be approved by the Committee or its delegates prior to release. The format should follow that set out in these Guidelines. There must be no reference to the name of the complainant.
- A corrective letter should be mailed in an envelope which states on the front surface “<Company name> Corrective Letter”
- A corrective advertisement must follow the same format as a corrective letter.

FIGURE 28: CORRECTIVE LETTER FORMAT

Dear Doctor

<Name of company> has recently been found in breach of the Medicines Australia Code of Conduct in relation to claims <include information on claim found in breach and name of product>

The Code sets the standard for the ethical marketing and promotion of prescription medicines in Australia and is available to all healthcare professionals (HCPs) on request from Medicines Australia or via its website at www.medicinesaustralia.com.au. As a member of Medicines Australia, <name of company> is committed to the highest ethical standards and has agreed to distribute this corrective letter as directed by the independent Medicines Australia Code of Conduct (and/or Appeals) Committee(s).

The Code of Conduct (and/or Appeals) Committee(s) reviewed <information>

<name of company> has agreed to withdraw the materials found in breach and to not use these materials or to make similar claims again.

< name of company> would like to apologise for any confusion that may have been created by the <name of product> promotional material.

Yours sincerely

Must be signed by the Managing Director or Medical Director

Principles for determining sanctions

The principles for determining a sanction should be transparent to both the complainant and subject company.

These principles are not a list of procedural rules but the foundation upon which the level of sanction is determined. Sanctions should be based upon clear principles and applied in a predictable and consistent manner without unnecessary rigidity.

Compliance with the Code is at its most effective when companies develop internal procedures for the development and approval of company activities and materials and ensure operations are based on an explicit risk management strategy. Companies should focus their efforts on good regulatory compliance rather than reliance on the complaints process.

It must be acknowledged that sanctions are not static. The upper limits of monetary sanctions will be reviewed as part of the triennial review of the Code. However, within the limits identified in the Code, the Code and Appeals Committees have the discretion to apply a range of monetary fines and other sanctions based on consideration of these principles.

The following is a set of principal factors which will be taken into consideration by the Code and Appeals Committees in determining a sanction following a finding of breach/es of the Code.

Principal factors in determining a sanction:

The nature and extent of the activity/material

- whether the breach should have been clearly evident to the Subject Company;
- breadth of activity or campaign;
- length of time that the materials have been in use;
- the number and type of alleged breach/es; and
- circumstances in which the activity took place – and whether any explanation offered by the subject company.

Level of breach

- **Technical** – means a breach of this Code that refers to the type size that is specified in this Code or inaccurate or incorrect referencing.
- **Minor** – is a breach of this Code that has no safety implications to a patient's wellbeing and will have no major effect on how the medical profession will prescribe the product.
- **Moderate** – is a breach of this Code that has no safety implications to a patient's wellbeing but may have an effect on how the medical professional will prescribe the product.
- **Severe** – is a breach of this Code that will have safety implications to a 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.
- **Repeat of a 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.
- Multiple breaches
- Totality principle where the Code of Conduct and Appeals Committees find a number of breaches of the Code they will usually consider the aggregate of the breaches to determine whether a sanction should be imposed.
- The Code of Conduct and Appeals Committees may impose a sanction in respect of each breach of the Code but may choose to impose an overall financial sanction.
- Bringing industry into disrepute – This is regarded as a severe breach and therefore is likely to attract a higher sanction.

Other considerations

- extent of breach – how misleading, damaging, disparaging;
- potential for patient harm – such breaches usually require corrective action and may attract a higher sanction;
- direct to consumer advertising or misleading information to the general public – in general, activities directed to the consumer found in breach of the Code attract a higher sanction. Direct to consumer advertising is in breach of the Therapeutic Goods legislation;
- promotion of a un-approved indication or product also attracts a higher sanction in recognition that this would also breach the Therapeutic Goods legislation;
- extent of dispute resolution dialogue – demonstration of significant attempts to resolve a complaint prior to proceeding to the Code Committee may result in a lower sanction being applied; and
- potential costs to be incurred by a company for corrective action – the Committee will consider the overall monetary cost of the package of sanctions, for example the cost of issuing a corrective letter in combination with a fine.

Company History

- history of previous breaches of the Code in relation to a specific therapeutic area;
- sanctions previously imposed on the company by the Code of Conduct and Appeals Committees in relation to the same or similar types of breach/es or in comparable circumstances;
- repeat breach;
- any evidence that previous breaches or sanctions have not successfully encouraged improved compliance within the company (not necessarily within the same therapeutic area);
- any evidence that the breach related to an activity that was not sanctioned by the company's operating procedures or training of personnel; and
- co-operation/acknowledgement of offence and evidence of internal procedures implemented to avoid similar breaches in future.

How to proceed if a company has not complied with a sanction

In the event that a pharmaceutical company found in breach of the Code does not comply with the sanctions imposed by the Code of Conduct and/or Appeals Committees the following action may be taken:

Sections 28.2 and 28.3 of the Code state that corrective action and a fine must be completed "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 corrective action has not been taken within the required time, the matter will be raised by a member of the Code Secretariat with the subject company and the matter may also be referred back to the Code Committee for their consideration.

Where a company found in breach of the Code advises Medicines Australia that they do not agree with the outcomes of the Code Committee and will not be complying with the sanctions imposed by the Code or Appeals Committees, the Medicines Australia Code Secretariat will arrange for a meeting to discuss the issues and encourage the company to comply with the decision of the Code Committee. Should this not resolve the issue, Medicines Australia will refer the matter to the Therapeutic Goods Administration (TGA) or the Australian Competition and Consumer Commission (ACCC), depending on the nature of the complaint.

Section 31.2 Monitoring Procedures

It is recommended that companies consider forming a Compliance Panel whose purpose is to review promotional material and planned activities for compliance with the Code of Conduct. This panel should consist of relevant individuals from departments such as medical, compliance, marketing and sales to ensure that all aspects of promotional material and activities comply with the Code of Conduct. These individuals should possess suitable qualifications and experience to undertake such tasks.

This panel should review promotional material from conception to release in final form or activities before they are undertaken.

Code Section 31.2.1 describes the scope of materials and activities that may be reviewed by the Monitoring Committee.

Code Edition 18 provides that member companies will only be required to provide promotional materials or information for review by the Monitoring Committee on no more than three occasions in a calendar year. If a member company responds to a request that it does not have any materials or has not undertaken any activities of the type specified in the request, this does not count as one of the three reviews for that company. The Secretariat will keep records of requests sent to member companies and their responses.

Companies must respond to the Monitoring Committee's request for further information when the Committee has undertaken a review of educational events, Advisory Board meetings, Consultancies or HCO support reports or similar reviews which have not required a company to submit information to the Committee. That is, if a company has submitted materials or information to the Committee for review three times in a calendar year, it must still respond to a request from the Committee for further information.

Monitoring Committee Submission Guide

Medicines Australia Monitoring Committee Material Requests

In accordance with Section 31 of the Code, the Monitoring Committee reviews selected promotional materials or activities. Companies must submit 10 copies of the materials as per the request letter. To ensure that Committee members have sufficient time for them to properly review the materials prior to their meeting, all hard copies of the materials must be received at Medicines Australia by close of business on the due date.

Format for submissions

Companies are requested to submit **10 collated copies** of all materials. Each collated copy should:

- include a summary sheet that clearly outlines the contents of the pack. A template is provided with each request letter. Adapt the template to your requirements, but ensure that each piece is easily identifiable.
- have each item separated by either a divider or identified with a stick-on flag.
- be double-hole punched. Do not triple-hole punch materials because sometimes several companies' materials are combined into a single folder.
- avoid using plastic sleeves where possible.
- include a copy of the Product Information for each product with materials being reviewed.
- include your company name on the summary sheet and other written materials and/or logo to ensure easy identification of each submission.

The Committee may also request that members supply one electronic copy of each reference cited in materials. These can be included in the submission on an electronic storage device, such as a USB or CD or sent via email to secretarycodecommittee@medicinesaustralia.com.au.

Verification forms

Companies are reminded that a verification form must be submitted with each response. The form is included with the request letter and must be signed by the Association Representative (the company Managing Director or chief executive). Verification forms are also required where companies do not have any materials for submission.

These forms can be provided in hard copy in the submission, or emailed to the above email address.

How do I know what should be submitted?

The request letter from Medicines Australia will outline which particular activity or material is being reviewed. Further explanation on each request is outlined below, however if you still require further information, please call the Secretariat for assistance.

Advertisements in the print media

Items that are considered advertisements are those that meet the requirements of:

- Section 2.1.1 – Journal advertisements directed at healthcare professionals

Please note: this includes any advertisement whether printed in a hard copy journal or online publication such as an e-newsletter. It also includes all primary, secondary or short advertisements, company commissioned articles and advertisements in reference manuals.

Printed Promotional material

Items that are considered to be printed material are those that meet the requirements of:

- Section 2.1.2 – Printed promotional material provided to, or used for a discussion with, a healthcare professional
- Section 2.1.3 – Mailing of printed promotional material to healthcare professionals
- Section 2.1.4 – Promotional material for display purposes only

Please note: this includes detail aids, leave behinds, and other hard copy promotional material used by sales representatives in the course of their discussions with healthcare professionals. This type of Monitoring Committee request also includes any items of promotional materials that have been mailed to healthcare professionals, including any covering letters accompanying the promotional materials.

Electronic promotional material

Items that are covered under electronic promotional materials are those that meet the requirements of:

- Section 2.2 – Electronic and Audiovisual media including e-detail aids
- Section 2.4 – Advertsienments for healthcare professionals on company-controlled websites and in independent e-journals and e-Newsletters

This includes any promotional material displayed via a computer, iPad, tablet or other electronic device.

Media Releases – Healthcare professional media

Items that are considered media releases are those that meet the requirements of:

- Section 2.8.1 – Media releases (company initiated communication)

Please note: Any background information that was sent with the media release should be included in the submission. For example, any email covering note that is sent to journalists with the media release; any background information on healthcare professional or consumer spokespeople identified as being available for interview; any Q&A document or backgrounder on the medical condition associated with the product.

Media Releases – Lay media

Items that are considered media releases are those that meet the requirements of:

- Section 13.4 – Product specific media releases

Please note: Any background information that was sent with the media release should be included in the submission. For example, any email covering note that is sent to journalists with the media release; any background information on healthcare professional or consumer spokespeople identified as being available for interview; any Q&A document or backgrounder on the medical condition associated with the product.

Websites directed at healthcare professionals

Websites that meet the requirements of:

- Section 2.4.1 – company controlled websites for healthcare professionals

Please note: when making a submission, please provide a login that can be utilised by the Monitoring Committee which provides access to all areas of the site. A hard copy of the site map is also requested to enable the Committee to navigate the site easily.

Websites directed at the general public

Websites that meet the requirements of:

- Section 13.9 – Use of the internet (relationship with the general public)

Please note: when making a submission, please provide a hard copy of the site map to enable the Committee to navigate the site easily. If there is a website for consumers that is password-protected (such as for patients who have been prescribed a particular medicine), please provide a log-in that can be utilised by the Monitoring Committee which provides access to all areas of the site.

Activities/other requests

The Committee may request companies provide all materials associated with a specific activity (e.g. market research, websites, etc). The request letter will outline which Section of the Code the Committee will be reviewing the materials against.

Medicines Australia Code of Conduct Committee submission format

The guidelines for complaints are set out on Appendix 1 of the Code of Conduct.

Non-industry complainants are requested to submit a complaint in writing to Medicines Australia, and are encouraged to use the template available on the Medicines Australia Website (http://medicinesaustralia.com.au/code-of-conduct/lodging-responding-to-a-code-of-conduct-complaint/)

Intercompany Complaints

The following checklist should be used by companies when submitting or responding to a complaint to Medicines Australia. Companies should ensure that they have included sufficient detail in their complaint or response to assist the members of the Code of Conduct Committee in making their decision.

Submitting a complaint

- 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, supporting evidence is desirable;
- Supporting data should be cross referenced to specific claims alleged to be in breach and a rationale for each allegation;
- Where medical literature is cited, a copy of the literature must be included in the documentation;
- 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 any meeting (whether in person or by teleconference); and
- All complaints must contain the written endorsement of the Association Representative, Alternate Association Representative or, in the case of a non-member company, the Managing Director or head of the prescription medicines division.

How should the complaint be submitted?

- **20 collated sets** of the complaint (each set should be complete)
- Double-hole punched. Do not triple-hole punch materials.
- Clip each set together – no need to include in a file or folder
- Please avoid using plastic sleeves where possible. It is suitable to only to use plastic sleeves on materials that cannot be hole punched (e.g. thick detail aid or small leave behind)

Responding to a complaint

- **20 collated sets** in a 2-ring binder/folder (when determining the folder size please consider the size of the complaint which will be inserted behind Tab 3 in your folder)
- Please avoid using plastic sleeves where possible. It is suitable to only to use plastic sleeves on materials that cannot be hole punched (e.g. thick detail aid or small leave behind)

Folders **must** be submitted to Medicines Australia in the following format:

Section1 (Tab 1): Promotional material subject to complaint

Original copies of each item of promotional material or advertisement etc alleged to be in breach of the Code.

If original copies are not available, good quality colour photocopies may be provided in the actual size of the original materials (not photo-reduced or enlarged).

Section 2 (Tab 2): Copy of the Product Information

Copy of current approved Product Information for the product subject to the complaint

Section 3 (Tab 3): Complaint

An original copy of the complaint will be inserted into the complaint response folder by the Code Secretariat prior to distribution to members of the Code of Conduct Committee.

Section 4 (Tab 4): Subject Company response.

All information pertaining to the response (excluding the promotional material and the Product Information which are included in their respective sections) must be included behind Tab 4. All supporting documents are to be included in this tab, and appear immediately after the response submission. It is recommended that each supporting reference article and/or document is identified by a stick-on flag to assist the Committee to locate the relevant substantiating information easily.

Responses should include the following:

- 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 you wish to refer to a specific section of the study please identify the study 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 matter. If you are in agreement with the Complainant's recital of the intercompany dialogue please note this in your submission, but do not include another copy of this documentation;
- Evidence of early involvement of the Managing Director in any complaint should be provided; and
- All responses must contain the written endorsement of the Association Representative, Alternate Association Representative or in the case of a non-member company the Managing Director or head of the prescription medicines division.

Lodging an appeal

Medicines Australia will provide members of the Appeals Committee with the complaint folder used by the Code of Conduct Committee, and include additional material pertaining to the appeal. The appeal Committee's agenda papers contain the following, in this numbered order:

- Promotional item/s
- Product Information
- Complaint (in its entirety, as submitted)
- Response to the complaint (in its entirety, as submitted)
- Extract of the minutes from the Code of Conduct Committee meeting pertaining to this matter
- Appeal submission
- Response to appeal from subject company

Appeal document format (item 6 above)

- **12 collated copies** of all appeal documents from an industry appellant
- Double-hole punched. Do not triple-hole punch materials.
- Clip each set together – no need to include in a file as the documents will be added to the Code of Conduct complaint folder by the Code Secretariat (see above).
- Please avoid using plastic sleeves where possible. It is suitable to only to use plastic sleeves on materials that cannot be hole punched (e.g. thick detail aid or small leave behind)

FIGURE 29: MONITORING COMMITTEE PROCESS SUMMARY

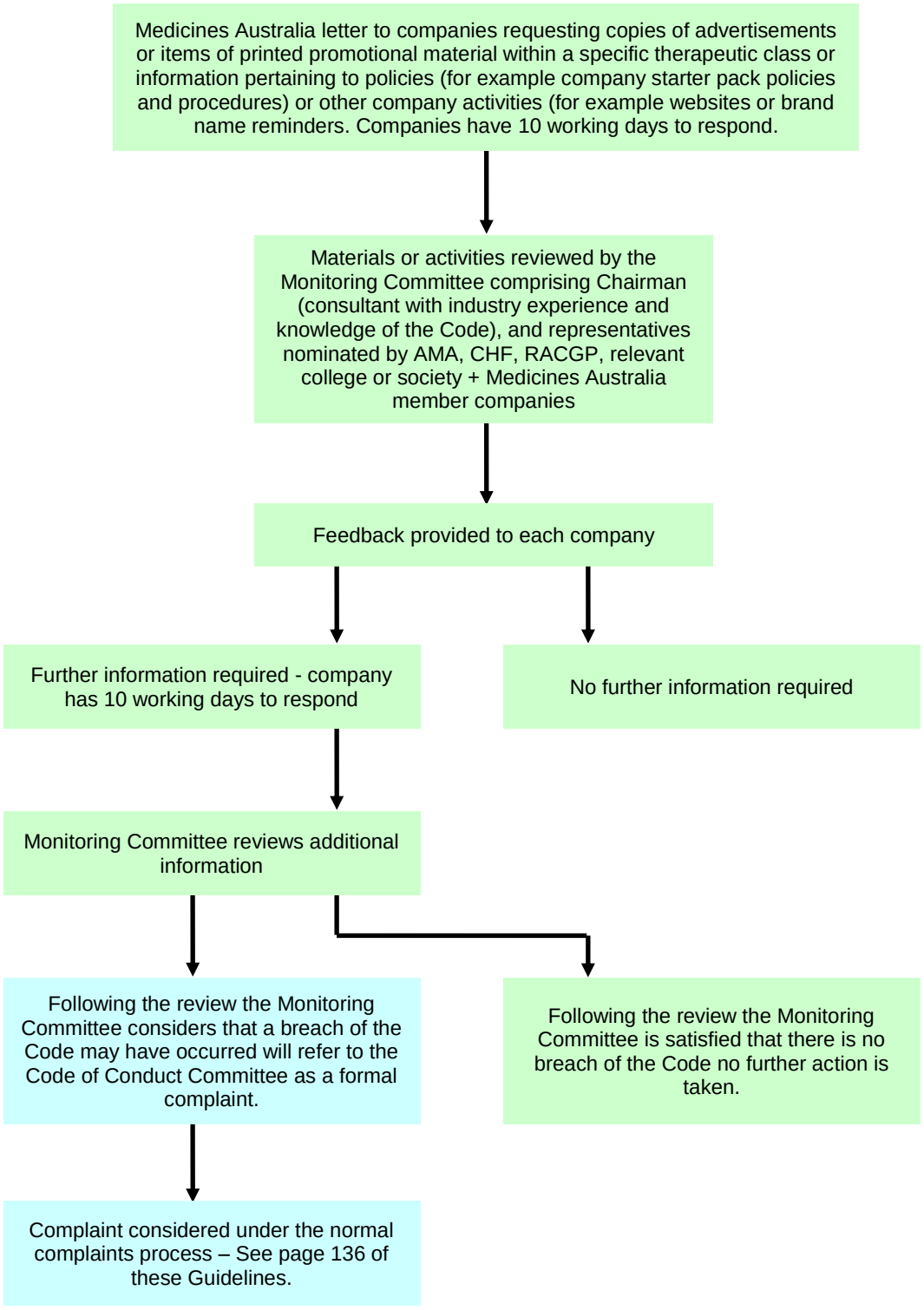


TABLE 11: SUMMARY OF MATERIALS AND ACTIVITIES REVIEWED BY THE MONITORING COMMITTEE BETWEEN 2011 & 2016

As a minimum the Monitoring Committee will review three types of promotional material and three different types of conduct covered by the Code each financial year. Table 9 provides a list of therapeutic areas and conduct reviewed by the Monitoring Committee since 2009.

TABLE 9: SUMMARY OF MATERIALS AND ACTIVITIES REVIEWED BY THE MONITORING COMMITTEE 2009-2014

	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
Alimentary System					
Cardiovascular System					
Central Nervous System					
Analgesia					
Musculoskeletal System					
Endocrine & Metabolic Disorders					
Genitourinary System					
Infections & Infestations					
Neoplastic Disorders					
Immunology					
Respiratory System					
Allergic Disorders					
Ear, Nose & Oropharynx					
Eye					
Skin					
Surgical Preparations					
Contraceptive Agents					
Reviews across all therapeutic classes	Patient Education and Patient Support Programs Company websites for healthcare professionals Disease Education Activities Product Specific media releases in the lay press	Educational Event Reports Corporate Websites Market Research Media Releases (HCP) CEP Audit Starter Packs	Educational Event Reports HCO Support Reports	Educational Event Reports HCO and Consultancy Reports Medical Education for HCPs Media releases to the general public	Educational Event Reports HCO Reports Product Familiarisation Programs Consent Forms Market Research Hospitality Procedures

Acknowledgements

Medicines Australia gratefully acknowledges the valuable contributions of the members of the Guidelines Working Group 2014-2016 in preparing this updated version of the Guidelines.

Working Group Members

- Mr Aaron Guttmann, Compliance and Ethics Lead - Australia/New Zealand, Bristol-Myers Squibb Australia Pty Ltd
- Mr Ian McKnight, Compliance Manager, Roche Products Pty Limited
- Ms Shane McSpedden, Head Medical Quality Compliance and Operations, Pfizer Australia
- Ms Helen Moss, Senior Project Manager - Medical Department, Servier Laboratories Australia
- Ms Julie Mullan, Medical Services Manager (Promotional Review), MSD (Australia)
- Dr Shaun O'Mara, Principal Medical Advisor, Novo Nordisk
- Ms Penny Tucker, Health Care Compliance Specialist, Janssen-Cilag Pty Ltd
- Mr Grant Villanueva, Compliance Manager, Australia New Zealand, AbbVie Pty Ltd
- Mr Gavin Walsh, General Manager, Princeton Health

Medicines Australia Secretariat

- Mrs Sophie Hibburd, Manager, Ethics and Compliance
- Ms Deborah Monk, Director, Ethics and Compliance

The Working Group and Medicines Australia would also like to acknowledge the support of Princeton Health in preparing and updating the graphics used in the Guidelines.