Annexure 1

MEDICINES Australia

CODE OF CONDUCT
EDITION 14

Code of Conduct
Edition 14
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Contents

Where to find assistance

Explanatory Notes have been provided throughout the Code to assist with its implementation at an operational level. The Explanatory Notes are based on the experiences with review of Code complaints, general inquiries, comments from Medicines Australia Members and determinations made by the Medicines Australia Board.

The "Code of Conduct Guidelines" have also been produced as a separate publication that will enhance a reader's understanding and application of the requirements of the Code.

The Code of Conduct and its Guidelines are available from Medicines Australia's website at www.medicinesaustralia.com.au or by contacting Medicines Australia on (02) 6282 6888.

Preface

The pharmaceutical industry* promotes the concept of good health, and a positive, health-oriented approach to daily living. Recognising that medicines play a vital role in the prevention, amelioration and treatment of disease states, the industry undertakes:

- to provide medicines that conform to the highest standards of safety, efficacy and quality;
- to ensure that medicines are supported by comprehensive technical and informational services in accordance with currently accepted medical and scientific knowledge and experience;
- to use professionalism in dealing with healthcare professionals*, public health officials and the general public.

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

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

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

A Member* of Medicines Australia. undertakes to comply with the Objects, the Rules* and the Code of Conduct of the Association*.

Complaints against any activity of a company should be made to the Chief Executive Officer* or his or her delegate , as provided for in the Code (Section 11 and Appendix 1).

It should be noted that the Therapeutic Goods Administration requires that promotional material (other than Product Information) for registered goods must comply with the requirements of the Code of Conduct and hence complaints can be made against non-Medicines Australia member companies (see Section 11.5).

If you are considering lodging a Code of Conduct complaint but are unsure of how to go about it, please contact Medicines Australia on (02) 6282 6888 for assistance.

Note:

A glossary of terms is provided at page 138. The first inclusion in the Code of a term defined in the glossary is denoted by an asterisk (*). Words that are defined in the glossary are underlined.

Preamble

(a) This Code of Conduct sets out standards of conduct for the activities of companies when engaged in the marketing of prescription products used under medical supervision as permitted by Australian legislation. The Code owes its origin to the determination of Medicines Australia to secure universal acceptance and adoption of high standards in the marketing of prescription medicines for human use.

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

(b) Acceptance and observance of the Code is a condition of membership of Medicines Australia. In accepting and observing the Code companies must comply with both the letter and the spirit of the Code.

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

Pharmaceutical companies which are not members of Medicines Australia are invited to accept and observe this Code and must comply with its provisions when required by the Therapeutic Goods Administration.

The Code shall be supervised and administered by the Board of Medicines Australia. Medicines Australia may issue determinations from time to time for the purpose of interpretation of certain sections of the Code. Complaints concerning alleged breaches of the Code should be reported to the Chief Executive Officer of Medicines Australia or his or her delegate.

Medicines Australia is also responsible for proposing amendments to the content of the Code of Conduct for adoption by its membership. Medicines Australia consults widely within its membership and with stakeholders regarding the Code of Conduct and welcomes any suggestions that will improve the Code's content and operation. Comments can be provided to Medicines Australia either by email to info@medicinesaustralia.com.au or by phone on (02) 6282 6888.

(c) A major guiding principle of the Code is that, whenever a promotional claim* is made for a product, it shall be accompanied by appropriate information based on the approved Product Information* for that product.

(d) The Code also reflects the industry's commitment that all activities with, or materials provided to health care professionals and members of the general public, must never be such as to bring discredit upon, or reduce confidence in the pharmaceutical industry. Such activities would be seen as a Severe Breach of the Code of Conduct.

(e) Failure to comply with the Code will result in sanctions being applied under the provisions of Section 12. Adherence to this Code in no way reduces a company's responsibilities to comply with the Trade Practices Act, Commonwealth and State Therapeutic Goods Acts and other requirements, legislation and Codes, including the IFPMA* Code. It should be recognised that the Medicines Australia Code is based upon the provisions of the IFPMA Code. Promotion* of prescription-only products to the general public is prohibited by law.

1. Nature and Availability of Information and Claims

1.1 Responsibility

It is the responsibility of companies, their employees and their medical/technical advisers to ensure that the content of all promotional and medical claims is balanced, accurate, correct*, fully supported by the Product Information, literature* or "Data on File"* or appropriate industry source, where these do not conflict with the Product Information.

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

1.2 Substantiating Data

1.2.1 Provision of Substantiating Data

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

Data in support of a claim, including "data on file" or "in press" must be made available without delay upon reasonable request.

Where this material is not available through standard library services, it must be made available without delay.

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

It is fundamental that any claim made must not be inconsistent with the Australian Product Information document, irrespective of the source on which the claim is based.

1.2.1 (a) All data to substantiate claims must be easily retrievable so that they could be supplied on request within 10 working days.

(b) Evaluated data* contained in an application for marketing in accordance with the current or previous Therapeutic Goods Administration guidelines for the registration of products may be used to substantiate claims. Such data must be made available when requested to substantiate a claim. A statement that the data are "Confidential" will not be accepted.

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

(d) Data relating to the cost effectiveness of a product may be used to substantiate promotional claims, however these data must conform with Sections 1.1, 1.2, 1.3, 1.5 and 1.7 of this Code.

Provisions of the Code

1.2.2 Level of Substantiating Data

Any information used to support a medical or promotional claim must include sufficient detail and be of adequate quality to allow evaluation of the validity of results and hence the claim.

Such substantiating information must not rely **solely** on data on file.

1.3 False or Misleading Claims

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

Claims must be referenced where there is a possibility that a reader may be misled if the source of the reference is not disclosed.

Explanatory Notes

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

For example, to satisfy the requirements of this section the evidence to support any major claim that will have a significant impact on the prescribing of a product, must be unequivocal and the highest quality. It should not rely upon evidence from sources such as poster presentations or abstracts that do not provide sufficient information to assess the veracity of the claim. Used appropriately these information sources may be used to support lesser or minor claims.

For further guidance regarding the application of this section please refer to the current Guidelines to the Code of Conduct.

1.3 The majority of breaches of the Code found concern this section. The following are examples of situations where material may breach the Code. This list is not all inclusive and is based on the experience of the Code of Conduct 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 comparative product) study in a manner which 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.

(continued)

1.3.1 Unapproved products and indications

Products that have not been approved for registration by the Department of Health and Ageing must not be promoted. However, samples of unapproved products may be displayed and educational material* made available at International Congresses* and Australasian Congresses in accordance with Section 6. This restriction also applies to unapproved indications for registered products.

1.4 Good Taste

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

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

1.5 Unqualified Superlatives

Unqualified superlatives must not be used. Claims must not imply that a product or an active ingredient is unique* or has some special merit, quality or property unless this can be substantiated.

The word "safe" must not be used without qualification.

1.6 New Products

The word "new" must not be used to describe any product, presentation, or therapeutic indication, which has been available and generally promoted for more than 12 months in Australia.

1.3 *(continued)*

(d) Suggestions or representations of uses, dosages, indications or any other aspect of the Product Information not approved by the Commonwealth Department of Health and Ageing.

(e) Shortening an approved indication (eg 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 does not necessarily predict clinical effects must be made on the same page and within reasonable proximity to the data in a manner that is not obscured by other material.

(g) Presentation of information in such a manner eg type size* and layout, which, to the casual reader could produce an incorrect perspective. The type size used for qualifying statements must not be less than 2mm. The qualifying statement must not be included with other reference material but must be situated on the same page as the original statement. The original statement and the qualifying statement must be linked by use of a readily identifiable asterisk or a similar symbol.

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

(i) Shortening the title of graphical representations reproduced from literature which alters the original author's meaning.

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

1.7 Comparative Statements

Comparison of products must not be disparaging, but must be factual, fair and capable of substantiation and referenced to its source. In presenting a comparison, care must be taken to ensure that it properly reflects the body of evidence and does not mislead by distortion, by undue emphasis or in any other way. "Hanging" comparatives — those which merely claim that a product is better, stronger, more widely prescribed etc must not be used.

"Data on file" when used to substantiate comparative statements must comply with the requirement of Section 1.2.

1.8 Imitation

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

1.3.1 Where a company has been formally advised by the Department of Health and Ageing that a product has been approved and its Product Information has been finalised, it is considered approved for registration for the purpose of this Code.

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

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

1.7 Pharmaceutical 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 clause is to prohibit unfair and unjustified comparisons with the products or activities of a competitor.

Where a claim of comparative efficacy or safety is made, it must not be based solely on a comparison of Product Information documents that does not reflect the general literature, as those documents are based on different databases and are not directly comparable. This applies to Australian as well as overseas Product Information documents.

Claims of comparative efficacy or safety should be substantiated with respect to all aspects of efficacy or safety. Where a comparative claim relates to a specific parameter, any claims must be clearly identified as pertaining to that parameter.

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

- the lack of significance must be stated explicitly; it is insufficient to state the p value

(continued)

1.9 Medical Ethics

Health care professionals' names or photographs must not be used in any way that is contrary to professional ethics.

1.10 Distinction of Promotional Material

Promotional material must be clearly distinguishable as such.

1.7 *(continued)*

- the data must not be used to generalise or to indicate superiority or inferiority

The statement that the claim is not statistically significant needs to be linked in some manner to the original claim, made on the same page and within a reasonable proximity of the original claim in a manner that is not obscured by other material using a type size of not less than 2mm.

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

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

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

1.10 Advertisements in a journal* should not be designed to resemble editorial matter unless clearly identified as an advertisement. See also Sections 3.5 and 3.6.

2. Product Information

Certain types of promotional material described in Section 3 must be accompanied by Full Disclosure Product Information, Abridged Product Information or Minimum Product Information for Primary Advertisements.

Wherever required, Product Information must appear on a plain background sufficiently contrasting for legibility. Major headings should be easily identifiable.

Product Information must not be overprinted or interspersed with promotional phrases or graphics and must clearly identify any recent change of clinical significance* (See Section 2.4).

2.1 Full Disclosure Product Information

2.1.1 The size of the type for this information must not be less than 1 mm as measured by the height of the font's letter "e".

2.1.2 With the exception of Primary advertisements*, full disclosure Product Information must accompany all promotional material for a period of 24 months from the date of marketing approval of a new chemical entity* in Australia or longer, at the discretion of the company.

For new chemical entities listed on the PBS, the full disclosure Product Information must accompany all promotional material, with the exception of Primary Advertisements, for at least 12 months from the initial PBS listing date.

2.1.3 Where a Product Information document has been approved by the Department of Health and Ageing, that document must be used in full without alteration unless such alteration is approved by the Department of Health and Ageing. When used to accompany promotional material, it should appear under the heading "Approved Product Information".

2.1.4 Where a Product Information document has not been approved by the Department of Health and Ageing, the document must comply with the format described in the Australian Guidelines for the Registration of Drugs Vol 1. When used to accompany promotional material, it should appear under the heading "Full Product Information".

2. 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" faces; by use of upper case letters only; or by use of half-tone rather than solid print. Dark print on a light background is preferable.

The date on which Product Information was approved (full) and/or last updated (full or abridged disclosure) must be included.

2.1.4 The Product Information documents for some "grandfather" products have not been evaluated by the Department of Health and Ageing. However, such documents can be subjected to review by the Department of Health and Ageing if considered necessary, for example on safety grounds. Any complaints received about the content of such documents may be referred to the Department Health and Ageing.

2.2 Abridged Disclosure Product Information

2.2.1 The size of the type for this information must not be less than 1 mm as measured by the height of the font's lower case letter "e".

2.2.2 Abridged disclosure Product Information may be used after 24 months from the date of marketing approval of a new chemical entity in medical publications, except where Section 2.4.1 applies. For new chemical entities listed on the PBS, the full Product Information must be used for at least 12 months from the initial PBS listing date.

2.2.3 Abridged disclosure Product Information must accurately reflect the full disclosure Product Information but may be a paraphrase or precis of the full disclosure Product Information.

2.2.4 Under the heading "Abridged Product Information", the following shall appear:

(a) Approved indications for use

(b) Contraindications

(c) Clinically significant warnings

(d) Clinically significant precautions for use

(e) Clinically significant adverse effects and interactions

(f) Available dosage forms

(g) Dosage regimens and routes of administration

(h) Dependence potential of clinical significance

(i) Reference to special groups of patients (including Australian pregnancy categorisation if issued).

(j) boxed warnings*

Where the full disclosure Product Information does not include items under these headings, such headings are not required to be included in the document.

2.3 Minimum Product Information for Primary Advertisement

2.3.1 The size of the type for this information must not be less than 1.5 mm as measured by the height of the font's lower case letter "e".

2.3.2 The Minimum Product Information required by a Primary Advertisement is:

(a) An approved indication or indications for use together with the dosage and method of use

(b) A succinct statement of the contraindications, precautions and side effects, including any boxed warnings that may appear in the full Product Information

(c) A clear and unambiguous statement for prescribers to review the Product Information before prescribing

(d) A statement to the effect that full disclosure Product Information is available on request from the Company

2.4 Changes of Clinical Significance or the addition of a Boxed Warning

2.4.1 Where a change of clinical significance relating to product safety or the addition of a boxed warning is incorporated into the Product Information, it should be indicated in all representations of the Product Information for a period of 12 months from the date of change by an asterisk(s) to a footnote in type size of not less than 2mm:

Please note change(s) in Product Information

2.4.2 The full text of the changed section should be included in any abridged Product Information during this period.

2.4.3 Where a Company is not actively promoting the product, written advice of the change to Product Information should be forwarded to the appropriate healthcare professionals.

3. Promotional Material*

For products that have a "Boxed Warning" included in their Approved Product Information, all promotional material must include the Boxed Warning or include a prominent statement drawing attention to the Boxed Warning.

In addition, all promotional material covered by Section 3.1, 3.2, 3.3 (with the exclusion of 3.3.3), 3.4 and 3.5 must include a clear and prominent statement drawing the attention of the reader to any Pharmaceutical Benefits Scheme (PBS) listing and restriction or its non availability via the PBS.

3.1 Journal Advertising

Journal Advertising must conform with the requirements of one of the following categories. The information required for Sections 3.1.1, 3.1.2 and 3.1.3 must appear in each publication in a type size of not less than 1.5 mm as measured by the font's lower case letter "e" and should appear on a background sufficiently contrasting for legibility. The orientation of the text should be the same as that of the main text of the advertisement.

3.1.1 Primary advertisement*

3.1.1.1 A Primary advertisement is the type of advertisement that is mandatory for advertising of all new chemical entities or the advertising of new indications for 24 months from the date of first advertising in medical publications, or longer at the discretion of the company. Primary advertisements must also be used for at least 12 months following a change of clinical significance made to a product's Product Information. Primary advertisements may contain promotional claims that conform to the requirements of Section 1 of this Code.

3. Any limitations to the terms of PBS listing should be clearly disclosed and easily identifiable by a reader. No attempt should be made to minimise this disclosure as it should be a prominent feature of any promotional material and a genuine communication vehicle to advise prescribers of this important information. The disclosure of this information must accurately reflect the approved PBS listing but may be a paraphrase or precis of that information.

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.

To satisfy the requirements of this section the requirements for the disclosure of this information can be found in the current Guidelines to the Code of Conduct.

3.1 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.

3.1.1.2 A primary advertisement must contain the following within the body of the advertisement.

(a) The brand name of the product

(b) The Australian Approved Name(s) of the active ingredient(s)

(c) The name of the supplier and the city, town or locality of the registered office

(d) The Full Disclosure Product Information (see Section 2.1), Abridged Disclosure Product Information (see Section 2.2) or the Minimum Product Information for Primary Advertisement (see Section 2.3).

(e) All PBS listings, including any restrictions, as required in the preamble to Section 3

(f) A clear and unambiguous statement for prescribers to review the Product Information before prescribing

3.1.1.4 A primary advertisement is mandatory for the advertising of all new chemical entities or the advertising of new indications for 24 months from the date of first advertising in medical publications, or longer at the discretion of the company.

3.1.1.5 The full or abridged Product Information may be included with a Primary advertisement. If the full or abridged Product Information is included it should be placed adjacent to the body of the advertisement. Where it is not practicable to do so, the advertisement must carry a statement in type size not less than 2 mm as measured by the font's letter "e' to the effect of the following statement.

"Please review Product Information before prescribing. In this publication, Product Information can be found ...."

At the point ..., insert the page number in the publication where the information can be found or reference to an adequately referenced product information section or advertisers index.

Product Information in any form should form a fixed part of the journal.

3.1.1.2 (b) The Australian Approved Name should appear adjacent to the most prominent presentation of the trade name.

3.1.1.2 (e) See preamble to Section 3 and its Explanatory Note

3.1.1.4 The wording used to direct the reader to the location of Product Information may be varied but must contain a direction to review the Product Information before prescribing the product.

Loose leaf inserts will not satisfy the requirements of this section.

3.1.1.6 All primary advertisements must contain the current PBS dispensed price* which can be included with the mandatory text required for this type of advertisements as detailed in Section 3.1. If a specific indication is being promoted the price or prices relevant to this indication should be disclosed. If no specific indication is being promoted the price of all presentations should be listed.

3.1.2 Secondary advertisement

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

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

3.1.2.2 A Secondary advertisement must contain:

(a) The brand name of the product

(b) The Australian Approved Name(s) of the active ingredient(s)

(c) The name of the supplier and the city, town or locality of the registered office

(d) A clear and unambiguous statement for prescribers to review the Product Information before prescribing

(e) A statement to the effect that further information is available on request from the supplier.

(f) All PBS listings, including any restrictions, as required in the preamble to Section 3

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

3.1.2.2. (f) See preamble to Section 3 and its Explanatory Note

3.1.2.3 A secondary advertisement must also contain either:

(a) the Full Disclosure Product information (See Section 2.1), the Abridged Disclosure Product Information (See Section 2.2) or the Minimum Product Information for Primary advertisements (see Section 2.3)

or

(b) the location of the Product Information within the same publication either by reference to the location of the Product Information or a Product Information Index;

or

(c) the location of the Primary Advertisement contained within the same publication by reference to the advertisers index.

3.1.3 Short advertisement

3.1.3.1 A short advertisement is designed to remind a prescriber of a product's existence but must not contain promotional claims. The sole use of a short advertisement in any one issue of a publication that does not also contain a Primary advertisement is not permitted:

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

3.1.3.2 A short advertisement must contain:

(a) The brand name of the product

(b) The Australian Approved Name(s) of the active ingredient(s)

(c) The name of the supplier and the city, town or locality of the registered office

(d) A statement to the effect that further information is available on request from the supplier.

(e) All PBS listings, including any restrictions, as required in the preamble to Section 3

3.1.3.2 (b) The Australian Approved Name should appear adjacent to the most prominent presentation of the name.

3.1.3.2 (e) See preamble to Section 3 and its Explanatory Note

3.1.3.3 A short advertisement may contain:

(a) Up to 5 words describing therapeutic class*, but without the use of promotional phrases.

(b) Graphics

(c) A statement of available dosage forms.

(d) A statement referring to the location of Product Information in a reference manual.

(e) The website address of the company.

No other material is permitted.

3.1.4 Company Commissioned articles*

3.1.4.1 Company commissioned articles must be identified as such in a type size of not less than 1.5 mm as measured by the fonts letter "e".

3.1.4.2 The company which is responsible for the insertion of the Company Commissioned Article must be clearly identified at either the top or the bottom of the Company Commissioned Article in a type size of not less than 1.5mm as measured by the font's letter "e".

3.1.4.3 Company Commissioned Articles must conform to all relevant provisions of Section 1 of this Code.

3.1.4.4 Statements by third parties, which are quoted in Company Commissioned Articles, must comply with the requirements of this Section, particularly the requirements of Section 1 of the Code.

3.2 Reference Manual* Advertising

The Australian Prescription Product Guide and MIMS currently satisfy the criteria for reference manuals. For the purposes of this section, MIMS Annual, its Supplements and bi-monthly edition are regarded as one reference manual.

3.2.1 Primary advertisement — reference manuals

Primary advertisements in reference manuals shall conform to the requirements of Section 3.1.1.2 (a), (b), (c) and (e) of the Code. These advertisements must also include reference to the product's Therapeutic Class Number or to the page number on which the relevant Product Information is located.

3.1.4 Independently edited supplements which publish the proceedings of a recognised congress* are not considered as Commissioned Articles. It is recommended that if a company sponsors such a supplement this should be stated clearly in the supplement. If a company does sponsor the reporting of a congress or symposium this activity must comply with the requirements of the Code, particularly those contained in Section 1.

3.2.2 Short advertisement — reference manuals

Short advertisements in reference manuals shall correspond to the requirements of Section 3.1.3 of the Code.

3.3 Materials for use by Medical Representatives*

A major guiding principle of the Code is that, whenever a promotional claim is made for a product, it shall be accompanied by the Product Information. Where multiple forms of promotion items are intended to be distributed at one time, the Product Information must appear at least once.

3.3.1 Printed promotional material

3.3.1.1 Where an item of printed promotional material is demonstrated, on completion of the presentation, the Product Information must be offered to the individual reviewing the promotional material or, in a group situation, to the audience.

3.3.1.2 All printed promotional material must include the following information:

(a) The brand name of the product

(b) The Australian Approved Name(s) of the active ingredient(s)

(c) The name of the supplier and the city, town or locality of the registered office

(d) Full or abridged disclosure Product Information

(e) All PBS listings, including any restrictions, as required in the preamble to Section 3

3.3.1.3 The use of full disclosure Product Information is mandatory for promotion of all new chemical entities for 24 months from the date of first advertising, or longer at the discretion of the Company. Abridged Disclosure Product Information may be used subsequent to that period.

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

3.3.1.2 (b) The Australian Approved Name should appear adjacent to the most prominent presentation of the trade name.

3.3.1.2 (d) See Sections 2.1, 2.2 and 2.3 and Explanatory Notes

3.3.1.2 (e) See preamble to Section 3 and its Explanatory Note

3.3.1.3 The wording used to direct the reader to the location of Product Information may be varied but must contain a direction to review the Product Information before prescribing the product.

3.3.1.4 Where it is impractical to print the Product Information on the body of the promotional material, the promotional material will carry a statement to the effect of the following in a type size of not less than 2 mm.

"Please review Product Information before prescribing. Product Information accompanies this item."

The item is then to be accompanied by a full or abridged Product Information document.

3.3.2 Audiovisual promotional material

3.3.2.1 All audiovisual promotional material must be accompanied by a document which contains the following information:

(a) The brand name of the product

(b) The Australian Approved Name(s) of the active ingredient(s)

(c) The name of the supplier and the city, town or locality of the registered office

(d) Full or abridged disclosure Product Information

(e) All PBS listing, including any restrictions, as required in the preamble to Section 3

3.3.2.2 The use of full disclosure Product Information is mandatory for promotion of all new chemical entities for 24 months from the date of first advertising, or longer at the discretion of the Company. Abridged disclosure Product Information may be used subsequent to that period.

3.3.2.3 Where an audiovisual item is demonstrated, on completion of the presentation, the Product Information must be offered to the individual reviewing the promotional material or, in a group situation, to the audience.

3.3.2 This section applies to audiotapes and videotapes for private use by healthcare professionals or for demonstration purposes to groups of healthcare professionals.

3.3.2.1 (b) The Australian Approved Name should appear adjacent to the most prominent presentation of the trade name.

3.3.2.1 (d) See Sections 2.1, 2.2 and 2.3

3.3.2.1 (e) See preamble to Section 3 and its Explanatory Note

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3.3.3 Brand name reminders*

3.3.3.1 Brand Name Reminders must include the following information:

(a) The brand name of the product

(b) The Australian Approved Name(s) of the active ingredient(s)

(c) Where applicable, the notation "See Warning" or "See Boxed Warning" drawing attention to the boxed warning in the Product Information.

Brand Name Reminders may also include:

(d) a non-promotional logo, device or graph

(e) a simple non-qualitative or quantitative description of the therapeutic category or approved indication for the product

3.3.3.2 Brand Name Reminders are not to contain any promotional claims including promotional tag lines and or statements.

3.3.3.3 Brand Name Reminders will only be acceptable if it is possible to clearly and legibly display the product's brand name. Where the nature of a Brand Name Reminder is such that it is demonstrably and obviously impractical to display the Australian Approved Name(s) of the active ingredient(s) as required in Section 3.3.3.1, the Brand Name Reminder must be accompanied by a document containing the information specified in Section 3.3.3.1.

3.3.3.4 Where the nature of a Brand Name Reminder is such that it is demonstrably and obviously impractical to display legibly the notation "See Warning" or "See Boxed Warning" as required in Section 3.3.3.1, a Brand Name Reminder must not be used for that product.

Explanatory Notes

3.3.3 An individual Brand Name Reminder should only be of token value, should not bring discredit to the industry and should be chosen on the basis that the item is clearly a Brand Name Reminder and not any other promotional material such as printed promotional material. The nature of any Brand Name Reminder or its packaging must not have the capacity to be confused with a therapeutic good.

3.3.3.1 (b) The Australian Approved Name should appear adjacent to the most prominent presentation of the trade name.

3.3.4 Medical literature/reprints

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

a) the sponsor's products and

b) any competitor's products with which a comparisons is being made.

3.3.4.2 Quotations from medical literature or from personal communications must accurately reflect the meaning of the author and significance of the study.

3.3.4.3 Any reports from congresses, symposia or other medical meetings, sponsored by a member of the pharmaceutical industry must be a balanced, true and accurate reflection of the findings of that meeting.

3.3.5 Computer Based Promotional Material

3.3.5.1 Computer based promotional material must comply with all relevant provisions of Section 1 of this Code.

3.3.5.2 Where an individual product is being promoted the appropriate Product Information must be offered to an individual reviewing the promotional material, readily accessible via the computer based material or offered to an audience in a group situation on completion of the presentation.

3.3.5.3 Where the Product Information is included in interactive data system, instructions for accessing it must be clearly displayed.

3.3.5.4 Where promotional or medical claims are included in the computer based promotional material, details of the substantiating references must be readily accessible via the computer based promotional material.

3.3.5.5 All PBS listings, including any restrictions, as required in the preamble to Section 3 must be displayed within the promotional material to allow a prescriber to read and understand this information.

3.3.5.6 The type size and graphics used in all promotional material must be such that allows easy and clear legibility.

3.3.4 Healthcare professionals may request literature on subjects not covered by the Product Information such as non-approved indications. While it is not acceptable to routinely disseminate such literature where unsolicited, it is acceptable to provide such information on individual request, provided that the literature or accompanying communication clearly identifies that it refers to a product or indication not approved in Australia. If the product is approved in Australia it must be accompanied by the Australian Approved Product Information.

Reprints themselves do not need to be accompanied by Product Information, but Product Information must be included with any accompanying material (eg letter) or presentation made which make promotional claims.

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

3.3.4.3 In addition to those reports prepared by a company, this section applies to reports prepared by individuals on behalf of companies

3.3.5 Computer Generated Promotional Material

As a minimum, this section covers the following:

- Promotional material designed by companies to promote their products directly to healthcare professionals and includes such promotional tools as software programs used by Medical Representatives during interchanges with healthcare professionals.
- The use by companies of external computer generated programs to promote their products. This includes such programs as prescribing and dispensing software.

3.4 Television Advertising

3.4.1 Television Advertising is permitted for transmissions restricted to an audience of healthcare professionals. Television advertising must comply with all relevant provisions of Section 1 of this Code. Following the promotion, the following items must appear on one screen and are mandatory for all television advertisements irrespective of the other content of that advertisement or the length of time that the product has been advertised.

(a) The brand name of the product

(b) The Australian Approved Name(s) of the active ingredient(s)

(c) The name of the supplier and the city, town or locality of the registered office

(d) A statement to the effect:

"Please review Product Information before prescribing. Product Information and substantiating references can be obtained from (the Company) or by phoning (Telecaster's phone number)".

(e) All PBS listings, including any restrictions, as required in the preamble to Section 3

3.4.2 The MIMS Annual reference must include the Therapeutic Class numbers and may also include the page number on which the relevant Product Information is located.

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

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

3.4 The provisions of the Code as they apply to full journal advertising (Section 3.1.1) should be applied to medical television advertising.

However, as it is not practical to display the Full Disclosure or Abridged Disclosure Product Information in conjunction with a television advertisement the use of a screen containing mandatory information is required.

3.4.1 (e) See preamble to Section 3 and its Explanatory Note