3.5 Mailings*

3.5.1 Mailings must comply will all relevant provisions of Section 1 of this Code and Australia's Privacy Legislation.

3.5.2 The Full Disclosure or Abridged disclosure Product Information as applicable must be included in all mailings where promotional claims are made.

3.5.3 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.

3.5.4 Mailings should only be sent to those categories of health professionals that have indicated or can reasonably by assumed to have a need for, or interest in, the particular information. Requests by health care professionals to be removed from promotional mailing lists must be complied with promptly and no name restored except at specific request or with written permission.

3.5.5 Mailing lists should be kept up-to-date.

3.5.6 Exposed mailings including postcards, envelopes or wrappers must not carry matter which might be regarded as promotion to the general public or which could be considered unsuitable for public view.

3.5.7 Any accompanying material sent with a Mailing must comply with the requirements of the Code of Conduct as a stand-alone item.

3.5.8 All PBS listings, including any restrictions, as required in the preamble to Section 3 should be included in all mailings where product promotional claims are made.

3.6 Document Transfer Media

Unsolicited electronic transmissions or replicas thereof, must not be used for promotional purposes.

3.5 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.

Unsolicited reprints of journal articles must be consistent with the Product Information, and any covering letter should comply with Section 1.

3.5.6 The display of a product's brand name or Australian Approved Name alone on mailings directed towards health care professionals is not considered as promotion to the general public in this context.

3.5.7 For example a brand name reminder may be included with a mailing but must comply with the requirements of Section 3.3.3.as a stand-alone item in order to satisfy this Section.

3.5.8 See preamble to Section 3 and its Explanatory Notes.

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

Electronic transmissions encompass the use of facsimiles and electronic mail.

3.7 Competitions

3.7.1 Competitions must fulfil all of the following criteria:

(i) The competition is based entirely on medical knowledge or the acquisition of medical knowledge.

(ii) The prize is directly relevant to the practice of medicine or pharmacy.

(iii) Individual prizes offered are to be of low monetary value or be an item of educational material.

3.7.2 Entry into a competition must not be dependent upon prescribing, ordering or recommending of a product and no such condition shall be made or implied.

3.7.3 The conduct of competitions shall comply in all respects with relevant State and Federal regulations.

3.8 Gifts/Offers

No items or offers shall be offered or given to healthcare professionals, their families or employees unless they are items or activities sanctioned by the following sections of this Code:-

(a) Section 3.3.3 Brand Name Reminders,

(b) Section 3.7 Competitions,

(c) Section 6 Involvement in Educational Symposia, Congresses and Satellite Meetings

(d) Section 7 Sponsorship

(e) Section 10.2 Hospitality or

(f) Section10.3 Medical Educational Material

3.7 The value of prizes permitted to be used in competitions needs to be assessed on an individual basis. For further explanation regarding the application of this Section please refer to the current edition of the Guidelines to the Code of Conduct.

Prizes, which might be useful in the practice of medicine but are not specific to medicine or pharmacy must not be offered.

3.8 For further explanation regarding the application of this Section please refer to the current edition of the Guidelines to the Code of Conduct.

3.9 The Use of the Internet for Pharmaceutical Information

Medicines Australia supports the right of Companies to use the Internet as a means of providing accurate and scientifically reliable information on medicines in a responsible manner for the benefit of both patients and health care professionals. However, the promotion of products covered by the Code of Conduct to the general public via the Internet would breach Section 9.4 of the Code and various therapeutic goods legislation which stipulate that prescription medicines must not be promoted to the public.

An advertisement is defined as any statement which is intended (directly or indirectly) to promote the use or supply of a medicine. In providing information to members of the general public, companies must ensure that the intent of this action is informational and not promotional. Care needs to be taken by companies to ensure that material published is of the kind that it is reasonable to conclude that no intention of promotion exists.

The following provisions are applicable to information generated for use via Australian Internet sites.

3.9.1 Information available to the General Public

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

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

3.9.1.1 A brief non-promotional summary of the company's products available in Australia. This information should be current, accurate and balanced and must not be promotional. It must contain information about the product's precautions, adverse reactions, warnings and contraindications and interactions and may contain information about current research or clinical data that would assist members of the general public understand how this product works, its uses and compliance advice.

All information provided to members of the general public about prescription medicines must be in accord with the product's current Approved Product Information.

3.9.1.1 See the current Guidelines to the Code of Conduct for examples of the application of this Section.

3.9.1.2 A copy of the product's Consumer Medicines Information (CMI). CMIs must appear in their entirety. They must not be amended, abridged or displayed in a promotional manner.

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

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

3.9.2 Promotion to and the provision of Information to Health Care Professionals

3.9.2.1 Promotional material on products covered by this Code must be accessible only to health care professionals.

3.9.2.2 Promotional information provided on the Internet to health care professionals must be accessible only via a secure system that is designed to prevent access by members of the general public.

3.9.2.3 Any promotional material provided to health care professionals via this medium must comply with the requirements of Sections 1 and 3 of the Code of Conduct.

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

3.9.2.3 Where references to other information sources or Internet sites are made, Companies must take all reasonable steps to ensure that these information sources and Internet sites are appropriate and will enhance the appropriate prescribing, dispensing and usage of medicines in Australia.

3.9.2.4 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 medicines in Australia. When making such a reference or linkage a clear screen displaying the following statement must appear before the reference material is accessed:

- the information a reader is about to be referred to may not comply with the Australian regulatory requirements and that further information relevant to the Australian environment is available from the company or via the Approved Product Information

3.9.3 General

3.9.3.1 Where an Internet site includes information regarding a product, the address and identity of the Company should be provided.

3.9.3.2 The intended audience should be readily apparent on the site.

3.9.3.3 It should be made clear when the reader is leaving the site or being directed to a site that the Company has not developed.

3.9.3.4 It is appropriate for Companies to link their sites to the text of the Code of Conduct on the Medicines Australia's website. Such a linkage must not be used to imply that Medicines Australia endorses any part of the content of the Company's site but to provide information to members of the general public and health care professionals on the Code of Conduct and the standards it sets.

3.10 Advertising in Electronic Prescribing Software Packages

The following provisions are applicable to advertising included in electronic prescribing software packages. Advertisements for products covered by this Code can be included in electronic prescribing software.

3.10.1 All promotional claims made must be consistent with the Australian Product Information and must comply with the requirements of Section 1 of this Code.

3.10.2 All advertisements must provide easy access to the Australian Product Information for the product being promoted.

3.10.2 Medicines Australia also encourages the electronic availability of Consumer Medicine Information via prescribing software packages.

3.10.3 Primary Advertisement

3.10.3.1 Where advertisements contain promotional claims, they must contain the following within the advertisement itself or via the software package:

(a) The brand name of the product

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

(c) The name of the supplier

The following must also appear, and may be provided within the body of the advertisement or elsewhere on the screen via the software package:

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

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

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

3.10.3.2 If this information is disclosed via the software package it must appear immediately adjacent to the advertisement and must be clear and legible.

3.10.3.3 The city, town or locality of the registered office may be included in the advertisement but if not, must be readily accessible via the use of a direct link such as a hot link key.

3.10.4 Short Advertisement

3.10.4.1 Short Advertisements must not contain promotional claims but must contain:

(a) The brand name of the product

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

3.10.5 Where promotional claims are included in the advertisement, it must allow the ability for the identification and details of any substantiating references to be displayed in the body of the advertisement or accessed via a hyperlink or similar mechanism.

3.10.6 The type size and graphics used in all advertisements must be such that allows easy and clear legibility having regard to sizes and resolution standards of screens likely to be used.

3.10.7 All advertisements must be displayed for a sufficient period to allow for viewer comprehension and the ability to access references.

3.10.8 Consistent with current printed reference manual advertising, it is acceptable for software prescribing packages to display, at random, advertisements for products within the therapeutic class being reviewed by the prescriber.

3.10.9 Lists of products may be provided in the prescribing window, in alphabetic order, by brand name, by generic name or both.

3.10.10 As prescribing software packages may include information which could be shared with patients by prescribers, the content of any advertisements, particularly graphics, must be such as to not cause any offence, alarm or concern or give rise to unrealistic expectations of benefit when viewed by members of the general public, including children.

Advertisements should also not be designed to stimulate a patient's demand for the prescription of a particular product.

3.10.11 A company shall not negotiate or accept any offer from a software manufacturer to achieve a trigger or mechanism that results in the preferential presentation of its own product or a less favourable presentation of a competitor's product in a way that would directly influence a prescriber's choice.

4. Medical Representatives

4.1 All material for use by medical representatives must conform with the provisions of Section 3 of this Code. Verbal statements made regarding a product must also comply with the provisions of Section 1 of this Code.

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

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

4.4 Medical representatives should at all times maintain a high standard of ethical conduct and professionalism in the discharge of their duties.

4.5 Medical representatives must not employ any deception to gain an appointment.

4.6 Medical representatives should ensure that 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 health care professional. The wishes of an individual health care professional, or the arrangements in force at any particular establishment, must be observed by medical representatives.

4.7 Medical representatives including company agents must not use the telephone to promote products to health care professionals except with the consent of the health care professional.

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

4. Companies should ensure that Medical Representatives are familiar with the provisions of the Code. Particular attention is drawn to Section 3.3 on material for use by Medical Representatives, Section 5 on Product Starter Packs and Section 6 on Involvement in Educational Symposia, Congresses and Satellite Meetings* and Section 10 Relationship with Health Care Professionals.

4.3 The Medicines Australia's Medical Representatives Educational Program (MedREP) or Continuing Education Program (CEP) provides sufficient background to satisfy the general requirements of this Section.

4.5/6 Medical representatives may be used to obtain survey information in accordance with Section 8. However, the pretext of carrying out a survey to gain an extended interview should be avoided.

Provisions of the Code

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

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

4.10 All medical representatives who have been employed in the Australian prescription pharmaceutical industry since April, 1983 are required to have completed the MedREP Diploma course, The Continuing Education Program (CEP) or be currently undertaking the Continuing Education Program* (CEP).

4.11 All medical representatives entering the Australian prescription pharmaceutical industry for the first time must enrol in Module 1 of the Continuing Education Program within the first six months of employment. All five modules of the Program must be completed within two years of commencing Module 1.

4.12 All Product Managers* must complete the Code of Conduct Module within the first twelve months of commencement of employment as a "Product Manager".

Explanatory Notes

4.8 Where promotional material is used during the appointment, the Product Information which is required by the Code to accompany that material is sufficient to satisfy this Section.

The disclosure of any PBS listing information should be clear and distinct. No attempt should be made to minimise any limitations to the terms of listing. The terms of listing should be undertaken in a responsible manner to advise prescribers of this important information. The disclosure of this information may be via printed material that complies with the requirements of Section 3.

4.9 The provision of personal domestic type services and products to health care professionals, their families or practice staff would be a breach of this section. The provision of a meal, which complies, with the requirements of Section 10, would not be a breach of this section.

For further information on the application of this Section please refer to the current Guidelines to the Code of Conduct.

4.11 No exemptions will be granted for CEP as it has been designed to meet the needs of the Australian environment particularly those of health care professionals.

Product managers who have successfully completed MedREP will need to ensure they have undertaken and successfully passed the Code of Conduct Module in the CEP.

5. Product Starter Packs*

Care should be exercised by Companies that the distribution of Starter Packs is carried out in a reasonable manner including compliance with a number of Federal and State Laws and product registration conditions which control the supply and storage conditions of products.

5.1 Starter Packs of products may only be supplied at their request to medical practitioners, dentists and hospital pharmacists for use in accordance with Section 5.2.

Product Information and Consumer Medicine Information, when available, should be offered at the time of distribution or included in the product pack.

5.2 Starter Packs should only be supplied to medical practitioners, dentists and hospital pharmacists when required for any of the following reasons:

(a) for immediate use in the surgery for relief of symptoms, or

(b) for the use of alternative treatments, prior to a prescription being written, or

(c) for after hours use, or

(d) for gaining familiarisation with products.

5.3 Starter Packs should not exceed 1/3 of the PBS primary quantity for each strength of a product. For non-PBS products, Starter Packs should be no larger than 1/3 of the smallest trade pack. Where it is not practical to produce a 1/3 pack, the smallest trade pack may be used.

5. Companies should ensure that they are kept informed of any changes in Federal and State Laws concerning the supply of Starter Packs.

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

State legislation may limit the quantity supplied as a Starter Pack to less than 1/3 PBS quantity in which case the legislation must be adhered to.

Primary quantity means most commonly prescribed PBS quantity.

Provisions of the Code

5.4 The maximum quantity of Starter Packs to be supplied to a medical practitioner, dentist or hospital pharmacist must be at these health care professional's discretion, should reflect their needs until the next visit by their representative and should conform to any relevant Federal or State regulations. The medical practitioner, dentist or hospital pharmacist must write the quantity requested and sign the request/receipt form as required by Federal and State Legislation.

Explanatory Notes

5.4 Starter Packs left with receptionists for the attention of the medical practitioner, dentist or hospital pharmacists without a signed request will be in breach of the Code of Conduct.

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

Companies must keep all records of the request for and supply of Starter Packs for a period compliant with Federal and State legislation, in a way that they are available for inspection by appropriate authorities.

5.5 Representatives must take adequate precautions to ensure the security of Starter Packs in their possession. Companies should develop an appropriate recording system so that if a product recall is necessary, relevant Starter Packs will be included in the recall.

5.6 Starter Packs when sent by mail or courier must be packed so as to be reasonably secure against the package being opened by young children. When mail is used to forward Starter Packs, Registered Mail (or its equivalent) must be used. There must be nothing on the packaging which indicates the nature of the contents.

5.7 Distribution of Starter Packs in hospitals must comply with individual hospital requirements.

5.8 On request, Companies must promptly accept the return of Starter Packs of their products.

5.9 Primary labelling of all Starter Packs distributed must comply with the current Therapeutic Goods Order on labelling. Where practical, the primary label should allow sufficient space for the medical practitioner, dentist or hospital pharmacist to write or label patient details and dosage instructions.

6. Involvement in Educational Symposia, Congresses and Satellite Meetings

General Principle

This section covers:

- Congresses which are events sponsored and organised by a society, college, university or other non-company entity,
- Symposia which are scientific meetings sponsored by a company as an independent event or as a satellite to a congress and
- Satellite meetings which are meetings held in conjunction with international or Australasian congresses and are under the auspices of the society, college or other non-company entity

Educational meetings are important for the dissemination of knowledge and experience to health care professionals. Companies involved in these events must have the primary objective of the enhancement of medical knowledge and the quality use of medicines in Australia.

6. Refer to the current Guidelines to the Code of Conduct for assistance or contact Medicines Australia for advice.

6.1 Trade Displays

6.1.1 Trade Displays must be directed only to health care professionals.

6.1.2 A Trade Display must include, in a prominent position, the name of the sponsoring company.

6.1.3 Exhibitors must comply with all requirements of the sponsoring organisation when setting up and conducting a Trade Display.

6.1.4 Product Information for products being promoted must be available from the Trade Display stand.

6.1.5 Starter Packs must not be made available for collection from unattended Trade Display stands, nor be supplied to unauthorised or non-qualified persons.

6.1.6 Competitions that are held as part of a Trade Display must be consistent with the requirements of Section 3.7 of this Code.

6.1.7 All promotional materials used at Trade Displays must be consistent with the requirements of Sections 1.3.1 and 3.3 of this Code.

6.1 All promotional material used at Trade Displays must be consistent with the requirements of Section 3.3.

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

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

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

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

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

Please also refer to the Explanatory Note to Section 1.3.1 that discusses Australian unapproved products and indications.

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

6.1.5 See also Section 5.

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

6.1.6 See also Section 3.7

6.1.8 To encourage health care professionals to attend a Trade Display a Company may offer Brand Name Reminders (Section 3.3.3), involvement in complying competitions (Section 3.7), an item of Medical Educational Material (Section 10.2) or hospitality in accord with Section 6.2.

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

6.2 Hospitality*

6.2.1 Any hospitality provided by Companies either directly or by sponsorship or assistance to the meeting organisers of educational meetings, must be secondary to the educational purpose

6.2.2 For Educational Meetings directly organised by, and the responsibility of companies, all hospitality must be simple and modest and no entertainment should be provided.

6.3 Behaviour

The behaviour of company representatives at Educational Meetings must be able to withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste. The behaviour of company representative must be beyond reproach and must not bring discredit upon the industry.

6.4. Sponsorship or Involvement in Australasian Congresses

Companies may assist and make financial contributions to educational meetings organised by third parties and may sponsor the attendance of health care professionals at these meetings, if:

- the primary objective of the meeting is the enhancement of medical knowledge and the quality use of medicines in Australia
- any assistance or sponsorship provided will be used for activities that further that objective, which would not bring discredit upon the industry and are able to successfully withstand public and professional and community scrutiny and conform to professional and community standards of ethics and good taste

6.1.8 Gifts, cash payments and/or donations to charities or societies must not be offered to health care professionals to visit Trade Display stands.

6.4 Companies may work with organisers and provide sponsorship to ensure third party educational meetings are a success and provide a forum for the dissemination of information that enhances the quality use of medicines. However companies should be fully cognisant of the activities that their sponsorship is supporting and must critically examine these activities to ensure they:

- enhance medical knowledge,
- enhance the quality use of medicines
- do not bring discredit on the industry,
- could successfully withstand public, professional and community scrutiny
- conform to professional and community standards

(continued)

6.5 Sponsorship of Health Care Professionals

The selection criteria for sponsorship to allow health care professionals to attend Educational Meetings must be based solely on their interest in the area of medicines being discussed and their ability to communicate any relevant information to Australian health care professionals to enhance the quality use of medicines.

6.6 Venue Selection

Educational Meetings organised by or the responsibility of companies must be held in venues suitable for the attainment of the primary objective of enhancing medical knowledge and the quality use of medicines in Australia. The choice of venue must be able to successfully withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste.

6.7 Reporting

Any reports generated from these meetings must comply with the requirements of Section 3.3.4.3

6.8 Travel

The following applies to Companies sponsoring delegates travelling to, from and within Australia to symposia and/or congresses:

- Travel may be subsidised provided the meeting is directly related to the health care professional's area of expertise.
- Travel within Australia should be by Economy class unless there are circumstances where Business Class travel may be appropriate. For international travel, only Economy or Business class should be used.
- A reasonable level of accommodation expenses may be covered.
- Travel costs and expenses for family or travelling companion(s) must not be paid for or subsidised by the sponsoring Company.

6.4 *(continued)*

Companies must critically examine any hospitality or entertainment provided at third party educational meetings to determine whether their involvement would meet the standards set by this Section. For example, a breach of this Section would be found if a company provided sponsorship for a lavish conference dinner that included significant entertainment even if the company was not involved in the planning or conduct of the event. A Company may however provide sponsorship for a modest conference dinner at which a medically related keynote address is given.

6.6 Appropriate venues for congresses, symposia or press conferences would be conference centres or meeting facilities in city or suburban hotels or a country centre equivalent. The choice of venues in locations emphasising leisure and sporting facilities is prohibited.

A venue for a company sponsored or organised meeting would be considered acceptable if held at the same or similar venue as the congress which is being organised by a society, college, university or other non-company entity. If challenged on the choice of a venue, it would be required that the Company substantiate this choice.

Companies considering whether to provide sponsorship for health care professionals to attend a third party meeting must critically examine the venue for the meeting to ensure it is an appropriate venue as defined by the Code.

For advice on the application of this Section please refer to the current Guidelines to the Code of Conduct.

6.8 This provision covers the sponsorship of delegates as distinct from speakers at symposia and congresses.

For advice on the application of this Section please refer to the current Guidelines to the Code of Conduct.

7. Sponsorship

The Code of Conduct recognises the significant contribution of the pharmaceutical industry to the quality use of medicines in Australia through sponsorship of health care professional organisations and activities involving health care professionals.

The provisions of this Section cover the sponsorship of any activities involving health care professionals by a company, including the attendance at international scientific and educational meetings.

7.1.1 Where Companies undertake the sponsorship of any health care professional activity such support must:

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

7.1.2 No sponsorship should be conditional upon any obligation to prescribe a particular product. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a health care professional's prescribing or dispensing practices.

7.1.3 Clear guidelines for the awarding of sponsorship must be developed and which are capable of being publicly disclosed if required. These guidelines must reflect the requirements of Section 7.1.1.

7.1.4 Sponsorship of educational meetings and sponsorship of health care professionals to attend these meetings must comply with the requirements of Section 6.

7. Companies must be fully aware of the activities that any sponsorship will support and be satisfied that they meet the standards established in this section. Sponsorship must not be used to avoid the requirements of Section 6, 7 and 10.

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

8. Research

The following provisions apply to Research whether it is carried out directly by the Company or by an organisation acting under its direction. Companies must ensure that the requirements of Australia's Privacy Legislation are complied with during any research activity and that any research activities are undertaken by suitably qualified and experienced individuals or organisations.

8.1 Post Marketing Surveillance (PMS) Studies

8.1.1 Post-Marketing Surveillance Studies should have scientific or medical merit and objectivity and not be designed for, or conducted as, a promotional exercise.

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

8.1.3 When a Company is intending to carry out a Post-Marketing Surveillance Study it must advise ADRAC* of its intention.

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

8.1.5 Decisions by the medical profession to prescribe the product should be based solely on their clinical judgement.

8.1.6 No starter packs or free trade packs* should be distributed as part of the Post-Marketing Surveillance Study.

8.1.7 Any payment to the medical profession must be commensurate with the work involved and not based upon the number of prescriptions written.

8.1.8 Suspected adverse drug reactions noted during Post-Marketing Surveillance Studies must be reported to ADRAC in accordance with the current TGA "Guidelines for Reporting of Adverse Drug Reactions by Pharmaceutical Companies".

8.1.9 A prompt report on the outcome of the study should be provided to participating doctors and ADRAC.

8. This section does not apply to evaluations being carried out under the approval of the Drug Committees in hospitals.

When selecting individuals or organisations to undertake any research activities companies may wish to refer to the Market Research Society of Australia — Code of Professional Behaviour.

8.1 Companies' attention is also directed to the "Joint ADRAC-APMA Guidelines for the Design and Conduct of Company Sponsored Post-Marketing Surveillance (PMS) Studies".

8.2 Product Familiarisation Programmes (PFP)

8.2.1 Companies must ensure that all Product Familiarisation Programmes have the aim of allowing the medical profession to evaluate and become familiar with a product.

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

8.2.3 PFP should involve patients being treated for approved indications of the product.

8.2.4 Product Familiarisation Programmes should only be initiated in the first 12 months following first supply of the product approved for registration, the approval of new indications* or substantive changes to the product. PFP should not be carried out for a period exceeding 12 months.

8.2.5 Starter packs that comply with the requirement of Section 5, may be supplied free of charge for these programmes.

8.2.6 No formal protocol is required for PFPs and collection of data is optional, as is the intention of publishing a report.

8.2.7 Suspected adverse drug reactions noted during the PFP must be reported to ADRAC in accordance with the current TGA "Guidelines for Reporting of Adverse Drug Reactions by Pharmaceutical Companies."

8.3 Market Research

The sole purpose of these activities must be to collect data and not a means to promote to and/or reward healthcare professionals

8.3.1 Market Research studies must be clearly identified as such when the initial approach is made.

8.3.2 Any payment must be kept to a minimum and should not exceed a level commensurate with the work involved.

8.3.3 Promotion should not be represented as Market Research or research of any type.

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

General

Clinical trials of products approved for registration are not covered by the above categories and are considered to be subject to the TGA "Guidelines for Good Clinical Research Practice (GCRP) in Australia".

9. Relationship with the General Public

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

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

9.1 General Inquiries

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

9.2 Product Specific Media Statements

9.2.1 The purpose of a media releases is to provide current, accurate and balanced information about medicines available in Australia and therefore must include information about the product's precautions, adverse reactions, warnings, contraindications and interactions. The intent of such media releases must be educational and not to promote particular treatments to the general public.

A media release issued directly, or through conferences for the lay media to announce a new product or major indication approval to the public, will be allowed if the product has been registered for use in Australia and the medical profession has been supplied with the appropriate information.

The media release may include the product's trade name, the Australian Approved Name of the product, its approved indications, therapeutic class, launch date and a balanced and accurate discussion of the product's method of action.

The media release must indicate any PBS listings and restrictions or a notation if the product is not listed on the PBS. It must also be accompanied by a copy of the product's current Consumer Medicine Information or the direct website for information.

9.1 Where a specific request is made by a patient or a member of a patient's family about a product which has been prescribed, the Company may clarify matters using a Consumer Medicine Information leaflet or a patient aid as described in Section 9.6, but should otherwise recommend inquirers to consult their doctor.

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

Companies should ensure that any sponsored experts be fully briefed on the provisions of the Code where it may be expected that the expert may have direct contact with the general public or lay media.

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

This provision does not restrict companies from responding to key international developments such as landmark clinical trials but any response must be current, accurate and balanced and must not be promotional. The intent of this communication must be educational.

9.2.1 *(continued)*

The media release must be in language that reflects current community standards and must not include any material that could be considered promotional or comparisons with other products.

9.2.2 No other media releases relating to a specific medicine are permitted however it is acceptable to respond to both media inquiries and inquiries from members of the general public.

9.2.3 Media releases should not be accompanied by any material which encourages or is designed to encourage the use of any prescription medicines. Its purpose should be solely educational and informative.

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

9.3 General Media Articles

General media articles concerning specific prescription products must not be initiated by companies. However, information on medical conditions is allowed.

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

9.4 Promotion to the General Public

Prescription products may only be promoted to health care professionals. Any information provided to members of the general public must be educational. Any activity directed towards the general public which encourages a patient to seek a prescription for a specific prescription-only medicine is prohibited.

9.5 Patient Education

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

In addition, the following criteria should be satisfied.

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

9.2.4 Conduct by agencies engaged by Companies in relation to media releases and product launches will always be treated as conduct authorised by the Company.

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

9.4 Promotion of an insulin delivery device* to the general public is permitted.

9.5 Examples of patient educational material which could be used include:

(a) 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".

(continued)

9.5.1 The educational material must be current, accurate and balanced.

9.5.2 The educational material should not focus on a particular product, unless the material is intended to be given to the patient by a healthcare professional after the decision to prescribe that product has been made.

9.5.3 Educational material may include descriptions of the therapeutic category, medical condition and a discussion of the relevant clinical parameters in general.

9.5.4 The educational material must include the name and the city, town or locality of the registered office of the supplier of the material, but their location should not be given prominence.

9.5.5 The educational material must include a statement directing the patient to seek further information about the condition or treatment from his/her doctor. Such statements must never be designed or made for the purpose of encouraging members of the public to ask their doctor to prescribe a product.

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

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

9.6 Patient Aids

Patient aids which 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 of administration, precautions, special instructions and like information. It must not make comparisons or include promotional claims.

9.5 (continued)

(b) 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.

(c) 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.

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

i) Use of trade names that are used in a manner that promotes a product rather than as an informative and educational tool.

ii) Material which is not educational or contains medically incorrect educational material.

iii) Inclusion of response rates for a specific product or comparative claims.

9.7 Patient Support Programs

Companies may arrange or become involved in programs that support patients already prescribed a prescription-only medicine to improve positive health outcomes. To ensure that such activities could not be considered as promotional, companies must ensure that any statements made or material provided to members of the general public are not promotional and could not be considered as having the intention of promoting a prescription medicine to members of the general public.

Companies should ensure compliance with the following requirements if they are considering becoming involved in any patient support program:

- Any payment for the work undertaken by a health care professional in such programs is commensurate with the work undertaken
- No incentives, other than material that will enhance positive health outcomes and compliance, are provided to patients to become involved in these programs
- The program complies with all Australian privacy legislation
- All information provided to patients must comply with Sections 9.5 and 9.6 of this Code.
- The data collected from these programs will not be used for any other purpose other than to increase positive health outcomes and never for promotional activities.
- The duration of these programs is appropriate to the disease state treated by the product involved.

9.8 Discredit to, and Reduction of, Confidence in, the Industry

Activities with, or materials provided to 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.

10. Relationship with Healthcare Professionals

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

Financial or material benefits must not be offered to healthcare professionals to influence them in their prescribing or dispensing of pharmaceutical products.

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

This section is relevant to, but is not limited to, activities such as independent educational meetings organised by medical representatives or companies.

10.1 **Entertainment***

Interactions between Companies and health care professional must not include entertainment.

An exception to this requirement is that educational meetings of two or more days duration may include a modest opportunity for unstructured and individual recreational activities at the delegate's own expense.

10.1 In relation to Educational meetings of two or more days' duration, Companies may provide a period of time for unstructured, individual sporting or recreational activities at the delegates own expense. This period of time should be no longer than a half day. This period of time should not be the focal point of the educational meeting and should not be promoted as the primary focus of the meeting.

The organising of educational meetings to coincide with any recreational events or entertainment would be a breach of this section. The primary purpose and reasons for attendance for any interaction with health care professionals is to increase medical knowledge and enhance the quality use of medicines in Australia.

10.2 Hospitality

Any hospitality offered by Companies to health care professionals should be simple, modest, secondary to the educational content and provided in an environment that enhances education and learning. The venue and location at which a company provides hospitality to health care professionals must be conducive to education and learning and must not be chosen for its leisure or recreational facilities.

A Company must not subsidise or pay for the costs of family or companions of attendees at educational meetings.

10.3 Medical Educational Material

10.3.1 Materials supplied for medical education must include the name of the supplier and city, town or locality of the registered office.

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

10.4 General Remuneration

Any remuneration for services rendered should not exceed that which is commensurate with the services supplied.

10.5 Discredit to, and Reduction of, Confidence in, the Industry

Activities engaged in by Companies with health care professionals or materials provided to health care professionals must never be such as to bring discredit upon, or reduce confidence in the pharmaceutical industry. A breach of this requirement is a Severe Breach of the Code of Conduct.

10.2 The choice of venues in locations emphasising leisure and sporting facilities is prohibited. The choice of venues primarily used for sporting, cultural or artistic activities should be carefully scrutinised to ensure no entertainment is being provided either directly or indirectly.

Meals or any other hospitality provided by companies at an educational meeting should not differ to that expected at any professional business meeting and should reflect the professional standing of the audience. Examples of activities that would be seen as acceptable include:

- Medical education in conjunction with a simple lunch meeting in a surgery at which the catering could include the provision of sandwiches or takeaway food or what the health care professional would normally consume at a working lunch.
- Medical education given in conjunction with a meal outside a practice consistent with the quality expected by a professional attending a business meeting.

In relation to companions and family members it is unacceptable for a Company to pay for, subsidise or reimburse a health care professional for any costs, including but not limited to:

- Travel costs to and from any meeting
- Their accommodation costs at the meeting; or
- Any meals or hospitality they may consume at the meeting

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

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

For other examples please refer to the Guidelines to the Code of Conduct.

11. Administration of the Code

The administration of the Code shall be supervised by the Code of Conduct Committee, (hereinafter referred to as The Committee) which will be responsible to the Medicines Australia Board. Expert advice may be sought externally by the Committee in reaching a decision as to whether or not a breach has occurred.

11.1 Procedures

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

11.1.1 On the receipt of such information, the Chief Executive Officer of the Association or his or her delegate shall acknowledge the complaint in writing within five (5) working days of receipt. All such complaints shall be dealt with as expeditiously as possible.

The Company that is the subject of the complaint (Subject Company) shall be given full details of the information lodged with the Association. The Subject Company will be invited to state within ten (10) working days whether or not the information supporting the complaint is correct, and to give any answer or explanation, which may be deemed necessary. The Subject Company may obtain external advice in order to respond to a Code of Conduct complaint. If external advice is sought, all Code of Conduct documents must be kept confidential and can only be provided for the purpose of seeking such advice.

The Subject Company and complainant will provide the Association with whatever references or information is deemed by the Chief Executive Officer or his or her delegate to be necessary to fully investigate the complaint. The information and response shall be provided to the Code of Conduct Committee.

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