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Code of Conduct

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Medicines Australia

Better health through research and innovation

Contents

Introduction

Medicines Australia leads the research-based pharmaceutical industry of Australia. Our members discover, develop, and manufacture medicines and vaccines that help people live longer, healthier lives and bring social and economic benefits to Australia. Our members invest in Australian medical research and take local discoveries and developments to the world.

Australia's innovative pharmaceutical companies support the quality and safe use of medicines. In doing so, we conduct ourselves ethically, ensuring that our communication is appropriate and relevant to those relying on our medicines, including patients, their carers and families, healthcare professionals, and the broader community.

This Code is a form of industry self-regulation; it sets an accountable standard for ensuring the Australian pharmaceutical industry acts with integrity and honesty to improve patient care. We hold ourselves to higher standards than other industries because we owe it to the patients who rely on our medicines. Patient trust is at the heart of our industry, and it is through our ethical behaviour that we build that trust, and respect the independence of healthcare providers, patients, and other stakeholders.

We join together, as Medicines Australia, to make sure that our conduct is of the highest standard and that the environment in which we provide access to our medicines is sustainable and fair. The Australian pharmaceutical industry promotes the safe and effective use of medicines as embodied in the National Medicines Policy, and is a recognised partner to support the Policy's aim, which is to ensure Australians have fair, timely, reliable, and affordable access to high-quality medicines.

Scope

The Constitution of Medicines Australia Limited provides that each Member Company must conform to and be bound by both the Constitution and this Code of Conduct. In addition, the Therapeutic Goods Administration states that, as a condition of registration, prescription medicines must be promoted in accordance with this Medicines Australia Code of Conduct, whether the Company is a member or non-member.

This Code of Conduct is underpinned by the Therapeutic Goods Act and Regulations and supports the application of the Act in the Australian regulatory setting for prescription medicines. The Code does not apply to clinical research activities.

Interpreting this Code

This Code of Conduct provides a principles-based framework for appropriate and ethical decision-making by companies when promoting prescription products and interacting with healthcare professionals, patient organisations, the general public and other stakeholders. It includes ten Overarching Principles that govern all activities covered by this Code, as well as more detailed provisions to support these activities.

To enhance understanding and application of this Code, Medicines Australia has created Guidance and educational resources which are hosted in the Code Tool Kit. Both the Code and the Tool Kit are available from Medicines Australia's website.

A Global Commitment

Medicines Australia is recognised as a global leader in ethical behaviour in the innovative medicines industry. Medicines Australia is a member of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). This Code incorporates the principles of the IFPMA Code of Practice. Further, Medicines Australia is a foundation signatory to the Australian Ethical Health Alliance's *Australian Consensus Framework for Ethical Collaborations in the Healthcare Sector*, which is available from the AEHA's website.

Where to find assistance

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

Ethics and Compliance Team, Medicines Australia
17 Denison Street, Deakin ACT 2600

Phone: (02) 6147 6500
Email: codehelpdesk@medicinesaustralia.com.au
Web: www.medicinesaustralia.com.au

To lodge a complaint, or for information on the complaints process, please email codehelpdesk@medicinesaustralia.com.au

PART A

Australian Pharmaceutical Industry Code of Conduct: Overarching Principles

In keeping with our commitment to ethical behaviour in the Australian pharmaceutical industry, Companies must ensure that these Overarching Principles are reflected in all activities covered by this Code.

1. **All activities undertaken by Companies have the purpose of supporting the quality use of medicines.**
2. **Companies are committed to transparency in their interactions with healthcare professionals and other stakeholders, to maintain trust and confidence in the industry.**
3. **As the primary repository of information relating to their products, Companies are responsible for providing current, accurate, balanced, and scientifically valid information on products to support their appropriate use. The same standards apply to all other Company communications.**
4. **Company employees, and anyone acting on behalf of a Company, will be appropriately trained on the Code and maintain a high standard of ethical conduct and professionalism in the discharge of their duties.**
5. **Consistent with our ethical undertakings, nothing is offered or provided by a Company in a manner or with conditions that would have an inappropriate influence on the approval, recommendation, prescribing, and/or use of a product.**
6. **Companies' interactions with all stakeholders are at all times professional, consistent with all legislative requirements, and appropriate to the information needs of the respective audience.**
7. **Information relevant to prescribing, in particular product and safety information, are clearly communicated in all promotional materials. Promotional materials are designed by Companies to not only create awareness of Therapeutic Goods Administration (TGA) approved medicines, but to support proper assessment of their risks and benefits.**
8. **All promotional claims are consistent with the Australian Product Information document, including claims about competitor products, irrespective of the source on which the claim is based.**
9. **All events, initiated or sponsored by Companies, are reasonable and appropriate with respect to hospitality, travel and accommodation, therefore upholding the integrity and reputation of the industry.**
10. **All activities undertaken by Companies are clearly identified to their audience as a Company activity by the inclusion of the Company's name and city/town of the Company's Australian office.**

PART B

Ethical Interactions with Healthcare Professionals

Section 1
Requirements for Promotional Claims Directed at Healthcare Professionals

Companies are permitted to promote prescription products to healthcare professionals so long as all information, claims and graphical representations are current, accurate, balanced, consistent with the approved product information, and do not mislead directly, by implication, or by omission. This responsibility relates to any information given or claims made about the product being promoted, other products, disease states or conditions.

a) Companies are responsible for ensuring that all promotional claims are referenced and that cited reference/s provide the appropriate level of evidence for the claim being made, reflect the body of evidence, and allow healthcare professionals to independently evaluate the validity of the results and hence the claim.

b) If qualifying statements are used with a promotional claim, they should be linked to the relevant claim with a readily identifiable symbol and appear directly below or adjacent to the claim. Qualifying statements must be prominent.

c) Companies are responsible for appropriately qualifying where claims are based on animal or laboratory data.

d) Any claims for clinical benefit need to be of a magnitude that is generally accepted as clinically meaningful and supported by the body of evidence.

e) The statistical significance of comparative claims must be clearly indicated.

f) Companies should consider the appropriateness of superlatives and ensure that, when used, the superlative is substantiated by the appropriate level of evidence.

g) Wherever a healthcare professional's name, image or a direct quotation from their presentation or unpublished communication is used in any kind of promotional material, the Company should ensure that the healthcare professional provides documented approval.

h) 'Hanging' comparative claims should not be used. Examples of 'hanging' comparatives include those that merely claim a product is better, stronger, or more widely prescribed.

i) Companies are responsible for having systems in place to ensure all data to substantiate claims is easily retrievable so that they can be supplied on request within 10 working days.

1.1 Balance

a) Companies are responsible for ensuring they provide balanced information on products to support their appropriate use consistent with the Product Information (PI).

b) Balanced promotional materials provide proportionate weight to the benefits and risks of a product, and they recognise that product and risk information are as relevant as any therapeutic, promotional, or non-promotional claim.

c) The presentation of risks should be appropriate to the complexity of the promotional material, the therapy area, stage of product lifecycle and support the product's appropriate use consistent with the PI.

1.2 Substantiating Data

a) Substantiating data should not consist solely of posters, abstracts, 'personal communication' or unpublished data, as these data do not provide sufficient information to assess the veracity of a claim. These data sources can be used as secondary references to support claims.

b) Substantiating data can consist of an 'in press' article or data on file where these references are available to be supplied on request and provide the appropriate level of evidence to support the claim. The use of 'data on file' may be appropriate as sole substantiation for a claim regarding prescribing frequency or cumulative patient exposure; however, it would not be appropriate as sole substantiation for a safety or an efficacy claim.

c) Substantiating data should be consistent with the body of evidence.

d) Selective use of consistent positive results while neglecting consistent negative results from a systematic review or meta-analysis is not appropriate.

e) Claims based on pre-specified secondary endpoints where the primary endpoints are not met in a particular study can be used if:

   i. consistent with the body of evidence; and

   ii. they accurately reflect the conclusion of the study; and

   iii. it is clear to a reader that the primary endpoint was not met.

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

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

h) Observational data may be used to substantiate a claim when the data is of high quality and represents the highest level of evidence available.

i) Animal or laboratory data are insufficient to be used as the sole evidence to support a promotional claim. If animal or laboratory data are used, a qualifying statement must appear identifying this type of data and acknowledging that such data do not necessarily predict clinical effects.

j) Claims based on statistical comparisons must include sufficient detail to enable the reader to understand the statistical significance of the data. The accepted level of statistical significance is $p < 0.05$ and for multiple comparisons will be lower, as specified in the study publication or published protocol when available.

k) If the results of a comparative study are not statistically significant, a qualifying statement must be included stating, in full, that the results are "not statistically significant".

l) If the results of a comparative study do not include a statement of the significance or lack of significance of the results, a qualifying statement must be included stating that the p value is not available.

m) Comparative claims based on studies reporting clinically important differences must include sufficient detail to enable the reader to understand the significance of the data. The minimum clinically important difference, when available and defined for the trial, is the accepted level of clinical significance.

Section 2
Requirements for Material Directed to Healthcare Professionals

Material directed to healthcare professionals refers to any material that is developed by the Company for distribution to healthcare professionals. Material may be distributed in any manner or form.

a) Companies are responsible for ensuring that materials directed to healthcare professionals covered by this section are only able to be viewed or accessed by healthcare professionals.

b) Promotional material must be clearly distinguishable as such.

c) In all material containing promotional claims, a healthcare professional must have access to sufficient prescribing information for them to appropriately prescribe the product for a person consistent with its approved use.

d) Presentation of Product Information (PI) qualifying statements, and references must be clearly legible.

e) Promotional material should be presented in such a way that visible information is accurate and consistent with the Code when read in isolation.

f) Companies may engage with the healthcare professional media for promotional purposes, including issuing media releases and developing advertorial content.

2.1 Required Inclusions for Product-related Materials

All promotional material for a product, whether or not the material contains a promotional claim, must include or provide access to sufficient prescribing information for a healthcare professional to appropriately prescribe the product for a person consistent with its approved use.

All types of promotional materials, in all media, must include:

a) Brand name of the product;

b) Australian Approved Name(s) of the active ingredient(s) placed adjacent to the most prominent presentation of the brand name;

c) Any boxed warnings and/or black triangle statement(s) as required by the TGA;

d) A statement directing healthcare professionals to review Product Information (PI) before prescribing. This statement should include the means for healthcare professionals to access the PI immediately in electronic or other form, or the telephone number for the Company medical information service;

e) A statement indicating the public funding or reimbursement status of the product, with or without details of listing, or a direction to where the relevant information is available;

f) Name of the supplier and the city, town or locality of the registered office; and

g) Date that the material was prepared or last revised.

2.2 Content Hosted Online

a) For materials hosted online that include promotional claims, whether hosted by a Company or a third-party, a mechanism such as password protection for system entry is consistent with ensuring online promotional content is only available to healthcare professionals.

b) Where Company-controlled websites reference and/or link to other information sources or internet sites, the Company is accountable for ensuring that these information sources and internet sites are appropriate and will enhance appropriate prescribing, disease state understanding, dispensing and usage of products in Australia.

c) Readers should be advised when leaving the site or being directed to a site that the Company has not developed, by displaying the following statement before the reference material is accessed: "The information a reader is about to be referred to may not comply with the Australian regulatory requirements. Further information relevant to the Australian environment is available from the Company or via the Product Information."

d) It is appropriate for Companies to make known on their websites that they are bound to an ethical standard through the Medicines Australia Code of Conduct, and provide a link to the Code. This is to provide information to healthcare professionals and other stakeholders on the Code of Conduct and the standards it sets, enhancing transparency and accountability, but should not imply any endorsement by Medicines Australia.

2.3 Prescribing Software

a) A Company should not place advertisements or promotional statements in prescribing software used by doctors. If such advertisements may be seen by patients/consumers during a consultation, this may contravene the Therapeutic Goods Act, which prohibits advertising prescription medicines to the general public. However, Companies may pay for the inclusion of non-promotional medical education for healthcare professionals, patient educational materials, and/or patient support program materials.

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

Section 3
Educational Material for Healthcare Professionals

Educational material includes resources and items of value directed at healthcare professionals and/or for use with educating patients.

a) Companies may provide medical literature, reprints and proceedings of educational events to healthcare professionals, but no part of a reprint or article should be specifically highlighted to draw the attention of the healthcare professional.

b) Companies do not offer items or gifts, which may inappropriately influence prescribing a product. The following are appropriate:

   i. Company-branded items, of low monetary value, relevant to the conduct of the educational meeting may be given to HCPs attending the educational meeting; and

   ii. Company-branded educational material.

Section 4
Events

Whether Company-initiated or sponsored, activities should be consistent with the Principles of the Code.

4.1 Company Educational Events Held in Australia

Where the Company initiates and manages the agenda, duration of educational content, and speaker selection:

a) The Company should be able to produce objective evidence of the educational value of the event (for example, an invitation or agenda) that clearly describes the purpose, content, meeting start and finish times and duration of educational sessions.

b) The educational program should be reviewed and approved through an internal Company process.

c) Companies should ensure that healthcare professionals speaking at Company-sponsored educational events or Congresses are aware of the obligation not to promote unapproved products or indications. This applies irrespective of whether the Company has provided the healthcare professional with a presentation or other material. Companies should be able to produce documentary evidence of this briefing and its content, which can be publicly disclosed if required. Briefing healthcare professionals giving presentations does not apply to independent third-party educational events or Company-sponsored educational events where an independent scientific faculty has chosen the topics and speakers.

4.2 Third-Party Educational Events Held in Australia

Companies are permitted to sponsor educational events which are organised by a society, college, university or other healthcare professional organisation to enhance medical knowledge and improve the quality use of medicines in Australia. These include 'in-institution' educational events, such as journal clubs, grand rounds, multidisciplinary and in-service meetings held within the healthcare professional's workplace.

a) The third-party organising the educational meeting should independently determine the educational content, select the speakers and attendees.

b) Companies should consider the objective evidence of the educational value of the event, including the event location and program, in deciding whether to sponsor the event.

c) Companies may sponsor a third-party educational event held at a venue selected by the third-party as long as the venue has appropriate facilities for holding educational events.

d) Financial sponsorship of an independent educational event should be paid to the organisation arranging, conducting or responsible for the event, and not to an individual healthcare professional.

4.3 Trade Displays

a) The amount paid to the educational meeting organiser for the trade display should be reported as sponsorship in accordance with the requirements of this Code.

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

c) Products not approved for registration in Australia must be approved for marketing in an overseas country targeted by the conference organisers. An appropriately worded label, prominently located, would be sufficient to satisfy this Section. Information regarding products not approved for registration in Australia, or non-approved indications for a product registered in Australia, must be consistent with Product Information in the country where the product is registered. Product Information must be available and distributed in accordance with the Code.

d) If the primary audience is broader than healthcare professionals, a Company should carefully consider whether the promotional trade display or the information to be made available from a trade display involves the promotion of products to the general public, which may contravene the Commonwealth Therapeutic Goods Act.

e) Companies hosting a trade display at a third-party scientific or medical conference where non-healthcare professionals have registered to attend should make reasonable efforts to request the conference organisers to include a note in the conference program that staff at Company trade displays are precluded by law from giving information about specific products to non-healthcare professionals.

4.4 Sponsorship of Healthcare Professionals to Attend Educational Event

a) Sponsorship may be provided to enable a healthcare professional to attend an educational event, provided the meeting is directly related to the healthcare professional's area of expertise, qualifications, experience, and educational needs.

b) In relation to the awarding of sponsorship to healthcare professionals, companies are responsible for establishing clear guidelines, which can be publicly disclosed if required, covering matters such as:

   i. Establishing the educational value of an event, including its location, program, and hospitality provided;

   ii. Appropriate reasons for providing such support;

   iii. The review and approval process for providing support, demonstrating that the support is independent of sales considerations; and

   iv. How to document all sponsorships, e.g. a written agreement with the healthcare professional.

4.5 Hospitality, Travel and Accommodation

Companies may provide hospitality, travel and/or accommodation to healthcare professionals in connection with activities or events. In doing so, Companies will ensure that they act in a manner which upholds the integrity and reputation of the industry and does not compromise the independence of healthcare professionals. Companies will also ensure activities and interactions with healthcare professionals can withstand public scrutiny.

The following principles apply to any activity for healthcare professionals involving the provision of travel, accommodation and/or hospitality:

a) A facility should be selected for its appropriateness to enable the activity to be conducted and should not be chosen or utilised for the purpose of leisure, sporting or recreational activities.

b) Companies may provide hospitality (food and beverages) if it is secondary to the purpose of an activity.

c) Any hospitality provided by a Company to a healthcare professional must be moderate and reasonable as judged by local standards, which in Australia is stipulated by a capped maximum spend per person. This amount is outlined in the Code Tool Kit.

d) Companies may not provide hospitality to a healthcare professional at their home or usual place of residence.

e) Companies may not provide entertainment to healthcare professionals.

f) Companies may provide accommodation to healthcare professionals attending a Company-sponsored/organised or independent educational event or undertaking a consultancy, provided it is reasonable and appropriate to the time and duration of the event or consultancy, and to the distance from where the healthcare professional usually resides.

g) Companies may provide travel only in direct association with educational event/s or to undertake a consulting service.

h) Companies may sponsor travel for healthcare professionals attending an international educational event in either economy or business class; domestic air travel and to New Zealand is by economy class only. The most direct route should be booked, without the allowance of more time at the destination than is reasonably justified to enable the healthcare professional to effectively participate in the event/s.

i) Companies should only support the attendance of the healthcare professional who are participating in the event or providing the service to the Company. It would be considered a gift or inducement if a Company was to provide hospitality, travel or accommodation to spouses, relatives, guests or companions of healthcare professionals and non-healthcare professional practice staff when they are accompanying a healthcare professional.

j) Companies should plan that any meal (food and beverages) provided in another country complies with the monetary limit set by the industry association in that country (where applicable). If there is no such limit in that country, any meal provided must be moderate and reasonable, following Australian principles.

Section 5
Financial Arrangements with Healthcare Professionals and Healthcare Organisations

Companies are responsible for ensuring consulting arrangements are consistent with the following:

a) A legitimate need for the services should be clearly identified in advance of approaching prospective consultants.

b) Records of the agenda, services provided, and contractual arrangements should be maintained by the Company, including meeting minutes (for an advisory board).

5.1 Remuneration

a) Companies are responsible for ensuring that all transfers of value are reasonable, appropriate, and balanced when considered in context.

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

c) A payment (including donations to charities or societies) must not be made to a healthcare professional as an incentive or in return for their attendance at an educational event or trade stand. Sponsorship to enable attendance at an educational event may be provided.

d) Financial or in-kind support must not be conditional on the use of a specific product (this exclude clinical research).

e) All transfers of value should be reported in accordance with this Code.

5.2 Grants, and Other Financial and In-kind Support

A Company may provide a grant, financial or in-kind support for a healthcare professional, medical practice, hospital, institution or health-related organisation:

i. to implement a quality use of medicine program; or

ii. for education, training or academic purposes; or

iii. for medical research; or

iv. to improve patient outcomes.

a) It is recommended that a grant or financial support should be paid to a medical practice or health-related organisation, rather than paid directly to an individual healthcare professional. A payment to an individual healthcare professional may create the impression that the purpose is not related to the quality use of medicines, education, research or improving patient outcomes.

b) A grant, financial or in-kind support must not be provided to underwrite a commercial business, generate income or pay for business operating costs for a practice or institution. Payment of an employee's salary, in part or full, is only acceptable to support a project or program for a defined period.

c) Clear guidelines which can be publicly disclosed if required must be developed in relation to the awarding of grants, financial and in-kind support.

d) A Company may temporarily loan a piece of equipment to a medical practice or health-related organisation, provided it facilitates the quality use of medicines and the company has a mechanism for retrieval of the equipment.

e) Items provided on permanent loan to a medical practice or health-related organisation could be regarded as a gift.

Section 6
Programs for the Provision of Registered Medicines at No Cost or Reduced Cost

Companies may offer programs for the provision of a registered medicine at no cost or reduced cost. These programs must be only for the purpose of enhancing patient access or enabling prescribers to gain experience with the product to improve patient care.

a) Companies may supply Starter packs at no cost or trade packs at no cost or reduced cost.

b) Companies must be aware of jurisdictional and individual institutional requirements for the supply, management and distribution of prescription products.

c) Programs must be reasonable and withstand public scrutiny with regard to the amount of stock, duration of program and any other relevant aspects of the program.

6.1 Product Starter Packs

a) Starter Pack definition and labelling requirements are specified under the current Therapeutic Goods Order.

b) Companies should ensure that they are kept informed of any changes in Commonwealth and State laws concerning the supply of starter packs. A summary of this information can be found in the Code Tool Kit.

c) Starter packs of products must be stored and supplied consistent with related product labelling.

d) Starter packs of products may only be supplied by representatives employed by the holder of a manufacturer's licence or wholesale dealer's licence or by authorised Company representatives.

e) A written request from a healthcare professional to receive starter packs, including the name and address of person supplied and the name, strength and quantity of the starter packs supplied, must be submitted prior to supply.

f) A record of delivery, including the quantity and nature of starter packs, should be kept for a minimum of two years by the Company.

Section 7
Scientific Exchange

Legitimate scientific exchange between appropriate Company personnel and healthcare professionals, the scientific community and other relevant stakeholders (such as payors, government officials) must be for the purposes of enhancing scientific understanding, improving patient care, improving access to medicines (including compassionate access), supporting quality use of medicines or assisting research and/or stakeholder budgetary planning.

The intent of such activities must be non-promotional with a focus on exchange being two-way communication.

a) It is reasonable where healthcare professionals or other relevant stakeholders are seeking clarity and/or additional information on products not approved in Australia and/or subjects not covered in the Australian Product Information, for Companies to provide such information.

b) It is reasonable for Companies to anticipate the needs of appropriate stakeholders for scientific and medical information. Such information/material must only be provided or made available to those stakeholders whose need for or interest in can reasonably be assumed for the conduct of their role. Material should be tailored to the audience to whom it is directed.

c) The Company Medical Department may engage in scientific exchange regarding unregistered products, uses or other off label topics. In some instances non-promotional roles, such as market access, regulatory affairs, may be permitted to engage in Scientific Exchange. Such exchange must be non-promotional in intent, content and nature and must be distinguished from promotional activities.

d) Scientific Exchange activities must be overseen by the Company Medical Director or their delegate.

e) Any information relating to unregistered products or off label topics must be clearly identified as such and must meet the requirements of this Code. Such materials must be approved by the Company Medical Director or their delegate.

f) In digital medical information applications, it is appropriate to provide healthcare professionals with information on unapproved products and uses when this information is only viewable after the healthcare professional executes a search that includes specific search terms relating to the unapproved product or use.

Section 8
Market Research

The following principles apply to all market research conducted by, or on behalf of, a Company.

a) Market research must be an initiative to collect relevant information to enhance the quality use of medicines and must not be used as a means to promote to and/or reward participants.

b) Market research may be undertaken about an approved or unapproved product or unapproved indication. For market research conducted with members of the general public, the product name and/or molecule should not be disclosed. Market research undertaken with patients who have been prescribed a particular prescription medicine may include product-specific questions.

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

d) Market research should not be implemented as competitions or quizzes or in any other manner that could lead to confusion as to the purpose of the market research.

e) Any transfer of value to a market research participant should be reasonable for the related services and consistent with upholding the integrity and reputation of the industry. Where a Company is aware of the specific named individual healthcare professionals participating in market research, payments must be disclosed in transparency reports in accordance with this Code.

Section 9
Company Representative Training

All sales representatives entering the Australian prescription pharmaceutical industry for the first time must undertake an endorsed Medicines Australia education program.

a) Sales representatives must enrol within the first six months of employment and complete the full program requirements for sales representatives within two years.

b) Any person who is directly involved in the development, review and approval of promotional materials and educational materials for the general public; or who has direct interaction with healthcare professionals for the purpose of promoting a prescription product or providing medical or clinical education must complete the Code of Conduct component of an endorsed Medicines Australia education program within the first 12 months of commencement of employment.

c) The requirement to complete an endorsed Medicines Australia education program applies equally to permanent employees or contracted employees. If a medical representative is employed or contracted on a part-time basis for a period of less than two years, they must be able to demonstrate that they are progressing through the education program in a timely manner and complete the program within the equivalent of two years of permanent employment.

PART C

Ethical Interactions with Relevant Stakeholders

Section 10
Appropriate Communications with Relevant Stakeholders

Communication with stakeholders who have a role in the research, development, registration, listing or monitoring of a therapeutic good is inherent in the National Medicines Policy and in the concept of the quality use of medicines. Companies are permitted to communicate proactively or reactively with relevant stakeholders, provided that discourse is limited to information that may assist the stakeholder in their role.

a) This communication is to be non-promotional and balanced in nature and is not to be made with the intention to inform patient-level prescribing, or any other clinical decision-making relevant to individual patients.

b) This communication should only be conducted by appropriately qualified and selected Company personnel.

c) It is appropriate for Companies to solicit information to assist in understanding relevant aspects of the healthcare environment relating to their products.

d) Relevant stakeholders include (but are not limited to):

   i. Members of a government or relevant government agency:

      a. any therapeutic goods regulator;

      b. any therapeutic goods reimbursor;

      c. any business regulator (ACCC, ASIC, etc.);

      d. parliamentarians and their representatives.

   ii. Patient organisations and patient advocacy groups;

   iii. Healthcare professional organisations;

   iv. Supply chain and distribution organisations;

   v. Current users of the product (patient/consumer) and their carers; and

   vi. The media.

10.1 Relationship with the Consumer Media and Product-specific Media Statements

It is appropriate for Companies to meet the information needs of the general public by providing current, accurate and balanced information about prescription products approved for use in Australia. The purpose of interactions with consumer media must be to enhance the quality use of medicines by providing appropriate, non-promotional information that is relevant to the Australian public.

a) Media organisations are wholly independent entities not bound by the provisions of this Code. As a result, while companies cannot control the final output of media coverage, Companies are responsible for ensuring that all their interactions with consumer media, including by any third-party acting on their behalf, are consistent with this Code and do not promote prescription products to the general public.

b) Product-specific media statements to consumer media may be issued when the information is relevant to the Australian public. Appropriate circumstances include announcement/s of a new product or new indication registration, new public funding such as a PBS listing, or a change to public funding. In consultation with the TGA, a Company may issue a media statement about issues such as product safety, shortages, recalls or withdrawal.

c) Companies may only issue each product-specific consumer media statement once, for each appropriate circumstance as described in paragraph 10.1 b), but it is acknowledged that this may be a single, coordinated release across multiple channels such as consumer media, patient organisations and via companies' digital channels.

d) A product-specific media statement announcing a new prescription product or new indication must not be made known to the general public until the product or indication has been registered in Australia and reasonable steps have been taken to inform healthcare professionals of its availability.

e) The product-specific media statement must contain all of the following:

   i. the product's brand name;

   ii. the Australian Approved Name of the active ingredients in the product;

   iii. its approved indications, relevant to the product-specific media statement;

   iv. therapeutic class;

   v. public funding status and restrictions, or a notation if the product is not publicly funded;

   vi. a summary of the side effect profile, product's precautions, adverse effects, warnings, contraindications, and interactions; and

   vii. a copy of, or a link to the product's Consumer Medicine Information.

f) A product specific media statement may also include:

   i. a non-comparative description of the mechanism of action;

   ii. price to the patient; and/or

   iii. date of product/indication availability.

g) A product specific media statement must not include:

   i. promotional statements or claims;

   ii. comparisons with other products;

   iii. quotes from experts, opinion leaders or patients that are promotional or comparative in nature;

   iv. an image of the product packaging;

   v. reference to a Company product access program; and

   vi. must not be accompanied by any material which encourages or is designed to encourage the use of any prescription product.

h) No statements or comments should be initiated by a Company regarding any products that are not registered in Australia but are available in overseas countries. This does not prohibit a Company listed on the Australian Stock Exchange issuing a non-promotional product specific media statement in line with the continuous disclosure requirements of the Australian Stock Exchange.

i) It is acceptable to respond to media enquiries or provide comment to a journalist or editor if a published article contains factually incorrect information provided this is done in an educative and non-promotional manner.

j) General media articles concerning specific prescription products must not be initiated by companies. Companies should not seek to encourage the publication of general media articles or its content with the aim of promoting their products but may, on request, provide educational material or review copy to ensure accuracy.

10.2 Social Media

All activities that utilise any social media platform will be considered in the same way as more traditional media activities.

a) Content that can be viewed by the general public should not advertise or include promotional claims for a prescription product.

b) Content that includes promotional claims for a prescription product must be restricted to a verified healthcare professional audience.

c) Companies are responsible for all content on Company-initiated and/or controlled social media sites and activities.

d) Content that does not conform to community standards of ethics and good taste, or which relates to unapproved products or indications, should be promptly removed.

e) It is appropriate for Companies to create content that enables its employees to appropriately engage in Company social media campaigns.

f) Companies should have policies and procedures which describe the roles and responsibility of its employees and contractors when interacting in the social media space to ensure compliance with the Code of Conduct.

Section 11
Engagement with Patient Organisations

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

a) When entering into relationships with patient organisations, Companies should refer to the Working Together – A Guide to Relationships between Health Consumer Organisations and Pharmaceutical Companies, published on the Medicines Australia website www.medicinesaustralia.com.au.

b) Companies should consider on a case-by-case basis whether any offer or proposal to collaborate with, or provide support to a patient organisation or any of its programs is capable of withstanding professional and public scrutiny.

c) The selection criteria for sponsorship to enable patients and representatives from a patient organisation to attend third-party scientific and medical conferences should be based on their specific interest in a therapeutic area.

d) Companies may share information with patient organisations and their representatives. This may include information about prescription medicines if there is a genuine need for the information, the content is relevant to their specific expertise and interest in the therapeutic area, and is non-promotional.

PART D
Ethical Interactions with Patients and the General Public

Section 12
Interactions with the General Public

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

b) Requests from individual members of the public for medical advice on the diagnosis of disease or choice of therapy must always be refused and the inquirer recommended to consult their doctor.

c) 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 in a non-promotional manner using the Consumer Medicine Information, relevant risk management materials or a patient aid and should otherwise recommend inquirers to consult their doctor.

d) Product-specific programs, product information, and patient aids should be provided only to patients already prescribed the product and must not be promotional. Items that are likely to be used outside the home, and thus visible to the general public, may be branded with a Company name and/or a Company logo only.

12.1 Promotion of Medicine Delivery Devices to the General Public

Promotion of a medicine delivery device to the general public is permitted in restricted circumstances.

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

12.2 Educational Information and Disease Awareness

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

In addition, the following criteria should be satisfied:

a) The information may include descriptions of the therapeutic category including classes but does not include any reference to a specific prescription product.

b) The information should be presented in a comprehensive, balanced and fair manner that does not unduly emphasise particular options or the need to seek treatment.

c) The emphasis of the educational information should be on the condition and its recognition rather than on the treatment options. The appropriate treatment for an individual patient is for the healthcare professional to decide, in consultation with the patient, and this should be clearly stated.

d) The tone of the material must not be presented in a way that unnecessarily causes alarm or misunderstanding in the community nor stimulate the demand for prescription of a particular product.

e) If readers of online material are referred or linked to other reputable information sources that the Company has not developed, before the information can be accessed a statement covering the following information, where relevant, should be displayed:

   i. the information they are about to be referred to may not comply with the Australian regulatory environment;

   ii. if relevant to a product, readers should refer to the CMI to understand the terms of a product's registration in Australia;

   iii. the intent of providing this further material is informational and not as advice; and

   iv. any information provided by this source should be discussed with their healthcare professional and does not replace their advice.

Section 13
Patient Support Programs (PSPs)

Companies are permitted to conduct programs, with or without involvement from a patient organisation, that aim to increase patient compliance with, and positive patient health outcomes from, their prescribed medical treatment.

a) PSPs must be designed to address a legitimate need, and the clinical rationale for the program should be documented.

b) Any communication with a patient enrolled in a PSP should clearly identify the Company and what materials or calls the patient may receive.

c) A Company may include information about the availability of a PSP and how to enrol in such a Program as an insert in the Product package. If an enrolment form is inserted in the Product package, there is no requirement for it to be reviewed or approved by the TGA, however it must not be promotional and must comply with this Code and the Commonwealth Therapeutic Goods Legislation. A package insert enrolment form must state: "the Patient Support Program is not authorised or approved by the Australian regulator of medicines, the TGA."

d) A Company may use individual patient data to report on whether the program delivers any improvement in compliance, for safety monitoring or to otherwise increase positive health outcomes, so long as the appropriate consents have been provided and all data is used in a de-identified manner.

e) Data from a PSP should never be used for promotional purposes.

f) Suspected Adverse Drug Reactions noted during monitoring of a PSP must be reported to the TGA in accordance with the current TGA pharmacovigilance responsibilities of medicines sponsors.

PART E

Ethical Interactions with Healthcare Professionals and with Consumers

Section 14
Transparency Reporting

a) Transparency reporting is a public benefit which provides visibility for consumers of payments and transfers of value made by Australian Companies:
   i. to Australian healthcare professionals who are engaged in patient care;
   ii. as a sponsorship of a third-party organisation to conduct educational activities for Australian healthcare professionals who are engaged in patient care;
   iii. as a grant or donation to a healthcare organisation; and
   iv. to patient organisations to deliver valuable services to Australian patients.

b) Reports on these activities must be published in accordance with the Schedule stated in this Code, using the templates contained in the Code Tool Kit. Companies may also make these reports available on their overall corporate or Australian corporate website.

c) An authorised Company representative will provide to Medicines Australia, within seven calendar days following submission of each required report, a declaration that the relevant report includes all payments and transfers of value required in this Code.

d) The information disclosed in these transparency reports must be publicly available for three years from the date of first publication.

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

f) Companies must comply with Australian Privacy legislation regarding the reporting of individual healthcare professional data. Each Company must establish a means to ensure maintenance of records which comply with Australian Privacy legislation.

14.1 Transfers of Value to Healthcare Professionals

Healthcare professionals provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and management experience. This expertise contributes towards quality use of medicines and improved patient care.

a) It is reasonable for healthcare professionals to be fairly compensated for legitimate expertise and services provided to the industry, and that such compensation be publicly disclosed by the pharmaceutical industry.

b) Transfers of value to healthcare professionals that must be reported are:
   i. fees paid to healthcare professionals in return for speaking at an educational meeting or event;
   ii. fees paid to healthcare professionals in return for consultancy or advisory services;
   iii. any remuneration or sponsorship of a healthcare professional as described in this Code. This does not include payments to consultants in relation to research and development work, such as the conduct of clinical trials.
   iv. any airfare, accommodation or registration fees directly associated with a meeting, consultancy or advisory service (whether held within or outside Australia); and

v. fees paid to healthcare professionals for the purpose of market research only where the identity of the healthcare professional is known to, or becomes known by, the Company. Reporting is not required where the Company contracting the market research is not involved in the selection of participating healthcare professionals and is not aware of the identities of those participating in the market research.

c) Reporting of all individual payments and transfers of value for each healthcare professional is required, indicating only the following information:
   i. date of the event or provision of service;
   ii. healthcare professional's name;
   iii. type of healthcare professional;
   iv. healthcare professional's principal practice address;
   v. description of the service;
   vi. description of the event;
   vii. whether the payment was made to the healthcare professional or a third-party; and
   viii. the amount of the payment or transfer of value subdivided into (where relevant) registration fees, travel and accommodation, and fees for service.

d) Where healthcare professionals request a payment for any of the above to be made to a third-party, these payments must still be disclosed for the individual healthcare professional, however, the report should identify that payment was made to a third-party. For the purposes of these reports, a healthcare professional is considered to have directly received the transfer of value of any registration fee, air travel or accommodation. Therefore, these transfers of value should be disclosed as being received by the individual healthcare professional, and not as a payment to a third-party.

e) Companies will provide the opportunity to review and submit corrections to the information. Healthcare professionals should have a period of at least six weeks to review, verify or correct collected information about payments and transfers of value.

f) Companies must not make a transfer of value unless they have taken appropriate steps to give notice of this disclosure obligation, so that the healthcare professional would reasonably expect the disclosure.

g) It is not the intent of transparency to capture or report payments or transfers of value to healthcare professionals that arise through the individual's employment by a Company.

h) Reports will be published in a central reporting system, Disclosure Australia, which will be searchable and downloadable in a format compatible with database management systems.

i) Reports will remain available for three years from the date of first publication.

14.2 Sponsorship of Third-Party Educational Meetings and Grants and Donations to Healthcare Organisations

It is reasonable for the pharmaceutical industry to financially support the education of healthcare professionals through sponsorship of meetings and symposia organised by third parties, and that such support is publicly disclosed. It is also reasonable for the industry to provide a grant or donation to a healthcare organisation in accordance with *Section 5.2.*

a) Each Company will provide a report to Medicines Australia on all sponsorships of independent educational meetings and symposia and grants or donations to healthcare organisations.

b) The following are examples of sponsorships of independent educational events that must be reported:
   i. financial sponsorship of a third-party educational event;
   ii. monetary contribution to support the conduct of grand rounds, clinic meetings or journal club meetings;
   iii. purchase space for providing a trade display at an educational event (including if this is the only sponsorship of the event).

c) If a Company only directly or indirectly provides hospitality (food and beverages) for an educational meeting, this is not reportable. However, the hospitality must comply with the requirements of this Code.

d) The following are examples of grants or donations that should be reported:
   i. disease awareness activities;
   ii. production of educational materials.

e) Sponsorship of clinical trials or clinical research is not reportable. Medicines Australia will make publicly available on its website the completed reports provided by each Company in accordance with the publishing dates specified in ***Section 14.4.***

f) It is the responsibility of a Company to inform a third-party organisation that any sponsorship, grant or donation provided will be publicly disclosed, including the monetary value of the funding.

14.3 Support for Patient Organisations

a) It is reasonable for Companies to provide financial support and/or significant direct or indirect non-financial support to organisations that work to benefit Australian patients, and it is appropriate for these activities to be reported.

b) To encourage consistency in the content and format of these reports, Companies should include:
   i. the name of the patient organisation;
   ii. a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the nature of the support; and
   iii. the monetary value of financial support and of invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value, the published information should describe clearly the non-monetary value that the organisation receives.

c) Medicines Australia will make publicly available on its website the completed reports in accordance with the publishing dates specified in ***Section 14.4.***

d) It is the responsibility of a Company to inform a patient organisation that any sponsorship received by the patient organisation from the pharmaceutical Company, whether sponsorship of the organisation, a specific publication, website or activity, and including the monetary value of the sponsorship, will be publicly disclosed.

14.4 Reporting Schedule

Reporting dates and publication dates are fixed. Adjustments are only made where the date falls on a weekend, in which case the date will be the Friday before.

Report type	Period covered in report	Data submission to Medicines Australia	Date published
Payments and Transfers of Value to Healthcare Professionals	1 January – 30 June	Due to Disclosure Australia 31 October	10 November
	1 July – 31 December	Due to Disclosure Australia 30 April	10 May
Third-Party Meeting and Symposia Sponsorship and Grants and Donations to Healthcare Organisations	1 January – 30 June	Due to Medicines Australia 31 October	10 December
	1 July – 31 December	Due to Medicines Australia 30 April	10 June
Patient Organisation Support	1 January – 31 December	Due to Medicines Australia 30 April	30 June

PART F
Code Governance

Section 15
Administration of the Code of Conduct

Medicines Australia is committed to the fair and ethical administration of the Code of Conduct, including the establishment of a Code of Conduct Committee (Code Committee), Code of Conduct Appeals Committee (Appeals Committee), and the Monitoring Committee. This Code sets out the requirements for undertaking each of these activities, and detailed guidelines for lodging a complaint, responding to a complaint, and raising an appeal can be found in the Code Tool Kit.

a) Medicines Australia provides a robust and independent complaint and appeal process where all parties are entitled to fair and equitable treatment. If these general principles are not met, the complaint may be returned for more information, or the review may be conducted in the absence of a complete response.

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

15.1 Acceptance of Complaints

a) A Complainant has the burden of proving their complaint on the balance of probabilities.

b) Anonymous complaints will not be accepted.

c) For Company-initiated complaints, Companies will follow the Intercompany Dialogue Standards, which are described in the Code Tool Kit. Medicines Australia will not accept a complaint from a Company unless it has been clearly demonstrated that intercompany dialogue has taken place and the complaint has not been resolved.

d) When a non-member Company submits a complaint, the non-member must lodge a bond of $20,000 with Medicines Australia.

e) The Code Committee has the discretion to refund all, part, or none of the bond in the event of finding no breach in relation to some or all of the matters subject to complaint. This bond will be retained by Medicines Australia to defray the costs of the Code Committee meeting and contribute to Code education programs.

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

g) Where substantially the same subject matter is, at the same time, subject to review by the TGA, or is the subject of legal proceedings between the same parties in an Australian court or Administrative Tribunal, Medicines Australia has the discretion to either not accept a complaint; or accept and delay referring a complaint to the Code Committee.

h) All documentation, including findings and/or sanctions of the Code Committee, shall remain confidential and shall not be released to any third-party, except if required by law, until the Subject Company and Complainant have exhausted all appeal procedures and the outcome of any appeal is known.

15.2 Complaints Process and Handling

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

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

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

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

d) If external advice is sought by a Subject 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.

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

f) After the Code Committee has concluded its deliberations and having made such further enquiry as necessary or desirable, the Chief Executive Officer or their delegate will:

   i. within two (2) working days of the Code Committee meeting notify the Subject Company and the Complainant in writing of the Committee's decisions.

   ii. within ten (10) working days of the Code Committee meeting provide reasons for the decision(s) of the Code Committee to the Subject Company and the Complainant which will include a full explanation for the decision made and the form of any sanction to be applied to the Subject Company.

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

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

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

15.3 Complaints against Non-member Companies

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

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

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

15.4 Frivolous or Vexatious Complaints

Medicines Australia takes its obligations of providing a fair and equitable complaints process seriously and will not tolerate misuse of the process.

a) If the Code Committee forms the view that a complaint might be considered frivolous or vexatious, it will request the Complainant Company to provide its response to the concern. The Complainant Company's response must be provided to Medicines Australia within ten (10) working days. The Complainant Company's response will be considered at the next Code Committee meeting or at an adjourned meeting of the Code Committee.

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

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

d) A Complainant Company that has had fines imposed by the Code Committee under this Section may lodge an appeal against the decision or fine, in accordance with the appeals procedures described in ***Section 15.7.***

15.5 Failure to follow Intercompany Dialogue Standards for Company-initiated Complaints

a) If it is alleged in a complaint or a complaint response that the Intercompany Dialogue Standards were not appropriately followed by either the Complainant Company or the Subject Company, the Code Committee may, but is not obligated to, request the relevant Company to provide its response to the concern. The Company's response must be provided to Medicines Australia within ten (10) working days. The Company's response will be considered at the next Code Committee meeting or at an adjourned meeting of the Code Committee.

b) A Complainant Company or a Subject Company may allege a breach of this section.

15.6 Sanctions

Sanctions may only be imposed where breaches of the Code of Conduct have been established. Sanctions may consist of one or more of the following:

Sanction	Description
Cessation of conduct and withdrawal	The Subject Company is required to take immediate action to discontinue or modify any conduct which is determined to constitute a breach of the Code, including the cessation and withdrawal of any promotional activity. Written notification of this action must be provided to Medicines Australia within five (5) working days of receipt of the reasons for the decision(s) of the Code Committee.
Corrective action	The Code Committee may require retraction statements, including corrective letters and advertising, to be issued by the Subject Company. The number, format, size, wording, mode of publication, prominence, timing (including duration of publication) and method of distribution of corrective statements must be approved by the Committee or its delegates prior to release. Corrective statements will, in general, specifically correct the statement found in breach of the Code and be in the form prescribed by the Committee. No other material may accompany such statements unless the inclusion of such material has been approved by the Code Committee or its delegates. Any corrective action required by the Code Committee must be completed within 30 calendar days of the receipt of the reasons for the decision(s) of the Code Committee meeting by the Subject Company (subject to any appeal that may be lodged under this Code). A Subject Company is required to provide a statement to the effect that the action has been undertaken together with a copy of the published advertisement or a copy of the final version of a corrective letter, signed by the Subject Company Managing Director or Medical Director.
Monetary fine	The Code Committee may impose a monetary fine on the Subject Company in accordance with the schedule of fines below.

The schedule of fines that may be imposed by the Code Committee or the Appeals Committee for breaches of the Code of Conduct is as follows:

Breach	Maximum Fine
Minor: • no safety implications to patients' wellbeing; and • no or minimal effect on how the medical profession will prescribe the product	$100,000
Moderate: • no safety implications to patients' wellbeing; but • may have a moderate effect on how the medical profession will prescribe the product	$150,000
Severe: • has safety implications to patients' wellbeing; and/or • will have a major effect on how the medical profession will prescribe the product; and/or • activities that bring discredit upon or reduce confidence in the pharmaceutical industry	$200,000
Severe breach where the activity has been completed before a breach is found and there is no opportunity for corrective action	$250,000
Repeat of previous breach	$250,000
Failure to complete corrective action in 30 calendar days	$50,000
Failure to follow Intercompany Dialogue Standards	$100,000
Frivolous or Vexatious Complaint	$100,000
Failure to pay a fine in 30 calendar days	$50,000

a) In the event that the Code Committee requires a Company to send a corrective letter or place corrective advertising, or pay a monetary fine, the Company shall at once comply with the Code Committee's ruling, subject to the outcome of any appeal against the decision of the Code Committee. Any activity or promotional material thus suspended shall not be reactivated or recommenced before the appeal process has been completed.

b) The Code Committee and the Appeals Committee have the discretion to apply a monetary fine for breaches of the Code individually or cumulatively. The fines above may be imposed for each identified breach determined under ***Section 16*** of the Code up to a maximum of $300,000 per complaint. By way of example, if a moderate breach and a severe breach were determined within one complaint, the Committee may impose a fine of up to $300,000.

c) Where a sanction has not been actioned in accordance with the decision(s) and the reasons for the decision(s) of the Code or Appeals Committee, the Code Committee may impose a fine of up to $50,000 for that breach of not completing the corrective action or paying the fine within the required period (30 calendar days).

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

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

   ii. publicise the failure of the Subject Company to take the corrective action.

15.7 Appeals

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

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

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

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

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

e) Either the Complainant or the Subject Company can appeal the findings and/or sanctions imposed by the Code Committee. Notice of an appeal by the Complainant or Subject Company must be made in writing within five (5) working days of receiving the decision(s) and the reasons for the decision(s) of the Code Committee. On receipt of an appeal the other party will be notified. The Complainant will be provided with a copy of the Subject Company's response to the complaint.

f) The Appellant must submit its written submissions in support of its appeal to Medicines Australia within a further five (5) working days. The written appeal will be provided to the other party, which shall make its written response to the appeal within ten (10) working days. The written appeal submission and any response to the appeal shall be provided to the Appeals Committee.

g) In the case of an appeal by the Complainant, the Subject Company's response to the appeal will be provided to the Complainant for review prior to the Appeals Committee meeting.

h) When a Subject Company or industry Complainant submits an appeal, the Company must lodge a bond of $20,000 with Medicines Australia. This bond is in addition to any bond lodged by a non-member Company when submitting a complaint to Medicines Australia.

i) The Appeals Committee has the discretion to refund all, part or none of the bond in the event of the findings and/or the sanction being removed or changed. This bond will be retained by Medicines Australia to defray the costs of the Code and Appeals Committee meetings and contribute to Code education programs.

j) A non-industry Complainant will not be required to lodge an appeal bond if it lodges an appeal against the Subject Company.

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

l) After the Appeals Committee has concluded its deliberations and having made such further enquiry as necessary or desirable, the Chief Executive Officer or their delegate will:

   i. within two (2) working days of the Appeals Committee meeting notify the Subject Company and the Complainant in writing of the Appeals Committee's decisions.

   ii. within ten (10) working days of the Committee meeting provide the reasons for the decision(s) of the Appeals Committee to the Subject Company and the Complainant which will include a full explanation for the decision made and the form of any sanction to be applied to the Subject Company.

m) A Complainant Company that has had fines imposed by the Code Committee under ***Section 15.4***, Frivolous or Vexatious complaints, may lodge an appeal against the decision and/or fine. The appeal, in writing, must be submitted to Medicines Australia by the Complainant within ten (10) working days of receiving advice of the reasons for the decision. This appeal will be determined by the Appeals Committee.

15.8 Monitoring

To promote compliance with the Medicines Australia Code of Conduct and thereby support the quality use of medicines, the Medicines Australia Monitoring Committee (Monitoring Committee) will proactively monitor conduct of Companies on a regular and ongoing basis. The Monitoring Committee will review activities that are less likely to receive public or another Company's scrutiny.

a) Companies will be required to submit to the Monitoring Committee an electronic copy of materials that were in use during a specified period of time.

b) The Monitoring Committee is empowered in any case to request, and Companies must provide, any further information concerning a Company's submission.

c) The Monitoring Committee's reviews will include, but are not limited to:

   i. Websites with access restricted to healthcare professionals;

   ii. Promotional materials;

   iii. Company policies and procedures to ensure compliance with Medical Representative training;

   iv. Company policies and procedures to ensure interactions and activities with healthcare professionals and other stakeholders comply with the Code.

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

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

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

Section 16
Committees

16.1 Membership of the Code of Conduct Committee

a) The following persons shall be eligible to be "full members" of the Code of Conduct Committee (Code Committee):

   i. Chair - Lawyer with competition and consumer law experience.

   ii. Three general practitioner representatives nominated by the Australian Medical Association (AMA), the Australian General Practice Network (AGPN), and the Royal Australian College of General Practitioners (RACGP).

   iii. A specialist physician nominated by the Royal Australasian College of Physicians (RACP).

   iv. A person nominated by the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT).

   v. A Consumer representative nominated by a patient organisation such as the Consumers Health Forum (CHF). Where a complaint is in relation to an activity or material directed at the general public or patients, a second consumer representative will be appointed.

vi. Where a complaint relates to an activity or material directed to the practice of pharmacy, a person nominated by any one of the Pharmacy Guild of Australia (PGA), the Pharmaceutical Society of Australia (PSA) or the Society of Hospital Pharmacists of Australia (SHPA) will be called upon.

vii. Up to a maximum of five representatives from Medicines Australia members or non-member Companies, drawn from the following, as relevant to the complaint. Where the Complainant Company or Subject Company is a non-member, one of the five representatives will be appointed from a non-member Company.

- Senior Executive Officers from Medicines Australia Members, as described in the Medicines Australia Constitution, or a non-member Company;
- Medical or Scientific Directors;
- Senior Compliance Officers;
- Marketing Directors.

b) Quorum

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

c) Observers

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

- One representative of the Therapeutic Goods Administration, as nominated by the Therapeutic Goods Administration;
- Observers nominated by Medicines Australia who would gain an educational benefit from attendance at a Code Committee meeting and who have no conflict of interest;
- Medicines Australia Chief Executive Officer or delegate.

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

d) Secretariat

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

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

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

16.2 Membership of the Appeals Committee

a) The following persons shall be eligible to be "full members" of the Appeals Committee:

i. Chair - Lawyer with competition and consumer law experience.

ii. A representative from the College and/or Society associated with the therapeutic class of the product subject to appeal, or a specialist with appropriate expertise as relevant to the appeal.

iii. A general practitioner representative, nominated by the AMA, RACGP and/or AGPN.

iv. A consumer representative, nominated by a patient organisation such as CHF. Where an appeal is in relation to an activity or material directed at the general public or patients, a second consumer representative will be appointed.

v. A person nominated by the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT).

vi. Up to a maximum of three representatives from Medicines Australia members or non-member Companies, drawn from the following, as relevant to the complaint. Where the Complainant Company or Subject Company is a non-member, one of these representatives will be appointed from a non-member Company.

- Senior Executive Officers from Medicines Australia Members, as described in the Medicines Australia Constitution, or a non-member Company;
- Medical or Scientific Directors;
- Senior Compliance Officers;
- Marketing Directors.

vii. Where a complaint relates to an activity or material directed to the practice of pharmacy, a person nominated by any one of the Pharmacy Guild of Australia (PGA), the Pharmaceutical Society of Australia (PSA) or the Society of Hospital Pharmacists of Australia (SHPA) will be called upon.

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

b) Quorum

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

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

c) Observers

i. In addition to the full members of the Appeals Committee, at the discretion of the Chair, the Medicines Australia Chief Executive Officer or delegate may attend a meeting of the Appeals Committee as an observer.

ii. Observers nominated by Medicines Australia who would gain an educational benefit from attendance at an Appeals Committee meeting and who have no conflict of interest;

iii. Subject to the discretion of the Chair, observers will be entitled to attend and speak at a properly constituted meeting of the Appeals Committee.

d) Secretariat

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

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

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

16.3 Membership of the Monitoring Committee

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

i. Chair – a consultant with industry experience in marketing and knowledge of the Code of Conduct.

ii. A general practitioner representative, nominated by the AMA, RACGP and/or AGPN.

iii. A representative from the College and/or Society associated with the therapeutic class of the material being reviewed.

iv. A consumer representative, nominated by a patient organisation such as the CHF. Where the review is in relation to an activity or material directed at the general public or patients, a second consumer representative will be appointed.

v. Up to a maximum of two representatives from Medicines Australia members, drawn from the following, as relevant to the subject matter under consideration for monitoring:

- Medicines Australia Member Company Senior Executive Officers, as described in the Medicines Australia Constitution;
- Medical or Scientific Directors;
- Senior Compliance Officers;
- Marketing Directors.

b) Quorum

A properly constituted meeting of the Monitoring Committee shall comprise no less than three full members, one of which must be a Consumer representative and one of which must be a representative of a Medicines Australia Member Company. All business of the Monitoring Committee will be conducted at a meeting of a properly constituted Monitoring Committee.

c) Observers

i. In addition to the full members of the Monitoring Committee, the following persons may attend a meeting of the Monitoring Committee as non-voting observers:

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

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

d) Secretariat

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

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

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

16.4 Procedure of Appointment

Medicines Australia will ensure the fair and equitable selection of members for the Code, Appeals and Monitoring Committees. Membership selection procedures are outlined in the Code Tool Kit.

16.5 Conflict of Interest

a) In advance of each Code, Appeals or Monitoring Committee meeting advice will be sought from all participants in the Committee as to whether there is any conflict of interest associated with the prescription product or activity subject to complaint, the Subject Company, the Complainant, or the material subject to monitoring.

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

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

16.6 Term of Appointment

a) Members of the Code, Appeals and Monitoring Committees, will be appointed for a period of three years and will be eligible for re-nomination at the completion of their term for a maximum of two (2) terms.

b) Committee Chairs are not subject to a term limitation however their appointment will be reviewed every three years.

Section 17
Code of Conduct Reporting

Medicines Australia is committed to the transparency of its conduct in administering the Code of Conduct. Medicines Australia will publish information relating to:

a) Complaints considered by the Code and Appeals Committee on its website within one month of the completion of that activity.

b) Outcomes of reviews conducted by the Monitoring Committee. This report will be published on Medicines Australia's website and will include the number of items reviewed and the number of items referred to the Code Committee.

Glossary

Advertisement is defined[1] as making any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design:

a) is on the label of the goods; or

b) is on the package in which the goods are contained; or

c) is on any material included with the package in which the goods are contained

Advertorial means[2] content that looks like editorial content but is published under a commercial arrangement between an advertiser, promoter or sponsor of goods and/or services and the publisher.

Advisory Board means a group of healthcare professionals with specific expertise contracted by a Company to meet to provide advice on a Company's product, group of products or general disease management.

Australian Approved Names means the active ingredients or chemical components of a product.

Australasian Congress means a congress held in Australia that is organised and controlled by an Australasian (or Australian and New Zealand) College or Society, or where a College or Society in New Zealand is actively organising and has joint control over the congress with an Australian Society or College.

Australian Privacy Legislation means the Privacy Act 1988 (Cth) and related legislation or any update to this legislation.

Balance refers to information that provides proportionate weight to the benefits and risks of a product.

Boxed Warning[3] is a mechanism adopted by the TGA to highlight special warning statements in the Product Information (PI) to the prescriber and patient that could significantly alter the risk for patients when prescribed the product.

Brand name for the purpose of the Code of Conduct has the same meaning as 'proprietary name' which is the registered trademark of the therapeutic product or the unique name assigned to the product.

Chief Executive Officer means that person appointed to manage the affairs of Medicines Australia Ltd in accordance with the Constitution of Medicines Australia.

Clinical research means planned research involving humans which is designed to investigate and report upon the effectiveness (including, but not limited to pharmacokinetics, dosage regimens, routes of administration, efficacy) and/or safety (including tolerability, immunogenicity, side effect profile, drug interactions) of a medicine.

Code of Conduct Secretary means that person appointed by the Medicines Australia Board to act as Secretary to the Code of Conduct Committee.

Code Tool Kit means the current Code of Conduct Resource Code Tool Kit.

Company means companies supplying prescription products in Australia.

Company representatives are those persons, including medical representatives, authorised by a Company to disseminate information about a product to healthcare professionals.

Competition means any activity that includes an element of chance or random selection.

Congress means an event sponsored and organised by a Society, College, university or other non-company entity.

Consultant means an Australian healthcare professional or a group of Australian healthcare professionals providing consulting services to a Company in relation to specific projects. For the purpose of reporting consultant services, these are regarded as different from providing advice as a member of an Advisory Board.

Consumers are persons other than healthcare professionals.

Consumer Medicine Information[4] (CMI) a leaflet that contains information on the safe and effective use of a prescription or specified over-the-counter medicine. A CMI document is written by the pharmaceutical Company (sponsor) responsible for the medicine.

Data on File is that body of unpublished clinical or scientific information held by a Company. It does not include evaluated data submitted to the TGA in accordance with the Australian Regulatory Guidelines for Prescription Medicines.

Educational material means any representation or literature which is intended to provide information about a medical condition or therapy which does not contain specific promotional claims.

Entertainment means the provision of any diversion or amusement.

General Public are persons other than healthcare professionals (see also Consumers).

Grants and Donations[5] collectively, mean providing funds, assets or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return.

Graphics means the use of any pictorial or graphical representation in promotional material, including photographs, drawings, x-rays, graphs and bar charts, but excludes any related promotional text.

Healthcare organisation means a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations) through which one or more healthcare professionals provide services.

Healthcare professional has the same meaning as 'health professional' in the Therapeutic Goods Act 1989 (Cth). This Code relates to healthcare professionals who in the course of their professional activities may prescribe, dispense, recommend, supply or administer a prescription medicine in Australia.

Health consumer organisations see **Patient organisation**s.

Hospitality means the provision of food and/or beverages.

IFPMA means International Federation of Pharmaceutical Manufacturers and Associations. The IFPMA represents the research-based pharmaceutical companies and associations around the world.

Information means educational facts regarding the attributes of a product.

Industry means all companies supplying prescription products in Australia.

International congress means a congress held in Australia where a Society or College in an overseas country is actively organising and has joint control over the conference with an Australian Society or College.

Journal means a serial publication whose distribution is restricted to the members of the healthcare professions.

Literature means that body of published trials, findings and reviews which have appeared in medical and scientific publications.

Market research is the gathering of data on the scope or dimensions of a market and its components, including the needs of the customers in that market.

Medical information websites contain information and standard responses prepared by a Company's medical information function in order to provide education or resources for Australian healthcare professionals. The website must not contain any advertising or promotional information.

Medicine delivery device is any device used for the administration of a prescribed product, including Schedule 3 products that are predominantly prescribed by a medical practitioner, that is distributed independently from the active ingredient. The device will be listed with the TGA as a device.

Medicines Australia endorsed education program means the professional training program developed by Medicines Australia. It is compulsory for all sales representatives employed by pharmaceutical companies to undertake this training. Also known as the Continuing Education Program (CEP).

Member means an entity registered as a Member of Medicines Australia Ltd.

Minor breach is a breach of this Code that has no safety implications for patients' wellbeing and will have no or a minimal effect on how the medical profession will prescribe the product.

[1] the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021*, or any subsequent version of this document

[2] Adapted from Australian Press Council 2005 (https://presscouncil.org.au/document/guideline-advertorials)

[3] https://www.tga.gov.au/publication/boxed-warning-guidance

[4] https://www.tga.gov.au/consumer-medicines-information-cmi

[5] EFPIA Code of Practice, 2019

Moderate breach is a breach of this Code that has no safety implications for patients' wellbeing but may have a moderate effect on how the medical profession will prescribe the product.

Non-Promotional Role is not commercial in intent, without likelihood to influence the intent to prescribe or use a product.

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

Patient Organisations (also referred to as **health consumer organisations**) are not-for-profit organisations, mainly composed of patients and/or caregivers, that represent the needs and interests of patients, their families and/or caregivers. They may range from small volunteer groups or large organisations, and generally promote views that are independent of government, the pharmaceutical industry and professional health service providers.

Patient Support Program (PSP) is a Company-developed program that is intended to assist patients in gaining benefit from their prescribed medical treatment, to improve health outcomes and promote the quality use of medicines.

Payor means an organisation or entity that pays for the healthcare products and/or services provided by a healthcare professional or healthcare provider. A payor may be a government entity which subsidises the cost of healthcare services and medicines (such as the Commonwealth Department of Health or a State or Territory health department) or a health insurance company.

Personal information has the same meaning as the *Privacy Act 1988* (Cth).

PBS means the Pharmaceutical Benefits Scheme of the Commonwealth Department of Health.

Prescribing software means a program on a healthcare professional's computer which is used in the decision-making process with a patient prior to generating a script. They may also contain patient records, Product Information, access to information on drug interactions and other educational information.

Product means any pharmaceutical dose form and/or delivery method that is approved for registration by the TGA for human therapeutic use, provided that such compound has been scheduled for sale or distribution by prescription only in at least one of the States of Australia or that such compound is primarily promoted to medical practitioners for the purpose of encouraging them to prescribe or recommend usage of that compound.

Product Information (PI) means either the current Australian Approved Product Information or in the case of a product whose registration pre-dates the current regulatory review ('Grandfathered Product') the document registered is known as the 'Full Product Information'. This Product Information must comply with the format specified in the TGA *Australian Regulatory Guidelines for Prescription Medicines*.

Promote means, in the context of the definition of 'advertisement', all informational and persuasive activities, the purpose, actual or likely effect of which is to encourage or discourage the purchase, sale, supply and/or use of therapeutic products[6].

Promotion, Promotional or Promotional claim means any statement made by a Company or Company's representative, whether verbal or written, which conveys the positive attributes of a product which extend beyond a simple non-qualitative or non-quantitative description of the therapeutic category or approved indication for the purpose of encouraging the usage of that product. It includes statements concerning efficacy, rate of adverse effects or other cautionary aspects of the product and comparative information.

Promotional material means any representation concerning the attributes of a product conveyed by any means whatever for the purpose of encouraging the usage of a product.

Quality Use of Medicines (QUM)[7] means selecting management options wisely; choosing suitable medicines if a medicine is considered necessary; and using medicines safely and effectively.

Reasonable means generally accepted by most people to be appropriate in the circumstances.

Registration is the issue by the TGA of an AUST.R number for a product approved for marketing in Australia in accordance with the Therapeutic Goods Act and Regulations.

[6] Adapted from: Ethical criteria for medicinal drug promotion. World Health Organization, Geneva, 1988

[7] The National Strategy for Quality Use of Medicines, Commonwealth of Australia, 2002

Repeat of previous breach means where the same or similar breach is repeated in the promotion of a particular product of a Company which had been found in breach.

Sales representative means a person expressly employed by a Company whose main purpose is the promotion of the Company's products to healthcare professionals.

Scientific exchange means the legitimate exchange of medical and scientific information, in a non-promotional manner, concerning (but not limited to) an unregistered product or use. This information or activity must be without any reasonable likelihood to influence the intent to prescribe or use a product and must not constitute promotion.

Severe breach is a breach of this Code that will have safety implications for patients' wellbeing and/or will have a major effect on how the medical profession will prescribe the product. A severe breach will also be found for activities that bring discredit upon or reduce confidence in the pharmaceutical industry.

Social media is an umbrella term that incorporates the various online platforms and activities that engage users to participate in, comment on and create digital content, and to allow them to interact, share information and network with others, including peer-to-peer conversations.

Starter pack means a small pack size of a product supplied at no cost to medical practitioners, dentists and hospital pharmacists. Starter packs are also referred to as 'samples' by healthcare professionals.

Substantiation means to give reasonable grounds in support of a promotional claim.

Supplier means the same as 'Company' – companies supplying prescription product in Australia.

Superlative means expressing the highest degree of quality or comparison.

Therapeutic class means the classification system used for defining and grouping products in an approved reference manual.

Therapeutic Goods Administration (TGA) is the Division of the Commonwealth Department of Health that is responsible for the regulation of therapeutic goods in Australia.

Trade Display means a display or exhibit of promotional or educational material about a product or products.

Trade pack means a package of a product which is sold by the Company.

Transfer of Value means a direct or indirect transfer of value, whether in cash, in kind or otherwise. A direct transfer of value is one made directly by a Company for the benefit of the recipient. An indirect transfer of value is one made by a third-party on behalf of a Company for the benefit of a recipient where the identity of the Company is known to, or can be identified by, the recipient.

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