

Medicines New Zealand



Medicines New Zealand Incorporated

Code of Practice

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Code of Practice, Edition 16

Effective from 5 August 2014

(The Code of Practice was first published in 1962).

Introduction

Medicines New Zealand Incorporated is an industry association that represents its member pharmaceutical companies in New Zealand.

Medicines New Zealand Vision

Innovative medicines and vaccines are recognised as leading health interventions that New Zealanders have access to when they need them.

Medicines New Zealand Mission

By December 2016, Medicines New Zealand will achieve sustainable influence on New Zealand pharmaceutical policy in order to realise optimal access to medicines and vaccines for New Zealanders.

The Medicines New Zealand Code of Practice

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

- to provide prescription medicines for human use that conform to the highest standards of safety, efficacy and quality;
- to ensure that medicines are supported by comprehensive technical and informational services in accordance with currently accepted medical and scientific knowledge and experience; and
- to be ethical and professional in all interactions with health care professionals (HCPs), public health officials and the general public.

The industry is committed to the quality use of prescription medicines and responsible prescribing, and urges that its products be used only in accordance with the directions and advice of HCPs. To ensure that information is available upon which to make informed prescribing decisions, it is necessary for companies to disseminate to HCPs the specialised product information gained during the research and development process, and from experience gained in clinical use. In doing so, a

company may draw attention to the existence and nature of a particular product by appropriate educational and promotional measures.

With the full cooperation of industry, there is now adequate legislation designed to ensure that all marketed products meet acceptable standards of quality, effectiveness and safety based on present knowledge and experience. While it is possible to legislate satisfactorily for the testing, manufacture and control of prescription medicines, appropriate standards of marketing conduct cannot be defined by the same means. For this reason, responsible manufacturers and distributors have collaborated to agree a code of practice, and share a commitment to improving the quality of patient care by ensuring appropriate interactions with HCPs, patients and patient organisations. Members of the pharmaceutical industry have a responsibility to provide on-going, objective and scientifically valid interpretations of data on prescription medicines to HCPs. The industry also has an obligation to provide appropriate non-promotional and promotional information on prescription medicines to members of the general public.

This Medicines New Zealand Incorporated Code of Practice (Code) represents an act of self-regulation. The Code sets out standards of conduct for the activities of companies when engaged in the marketing of prescription medicines used under medical supervision as permitted by New Zealand legislation. The Code incorporates the principles set out in the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Pharmaceutical Marketing Practices.

The purpose of the Code is to define and ensure high standards for the ethical and responsible promotion of prescription medicines in New Zealand, and wherever possible to exceed those required by law. The Code should be viewed as the minimum set of standards required to promote prescription products in New Zealand and does not in any way prohibit more stringent and comprehensive requirements being applied by individual companies.

Acceptance and observance of the Code is a condition of membership of Medicines New Zealand. In accepting and observing the Code, companies must comply with both the letter and the spirit of the Code. Companies should ensure that all agents acting on their behalf are fully conversant with the provisions of this Code. Pharmaceutical companies that are not members of Medicines New Zealand are invited to accept and observe this Code and must comply with its provisions when required by

the Advertising Standards Authority. Medicines New Zealand may issue determinations from time to time for the purpose of interpretation of certain sections of the Code.

A major guiding principle of the Code is that whenever a promotional claim is made for a product, it shall be accompanied by appropriate information consistent with the Medsafe approved Data Sheet (Data Sheet) for that product.

The Code also reflects the industry's commitment that all activities with, or materials provided to, HCPs and members of the general public must not bring discredit to, or reduce confidence in the pharmaceutical industry.

Failure to comply with the Code may result in sanctions being applied under the provisions outlined in the administrative section of the Code. Adherence to this Code in no way reduces a company's responsibilities to comply with relevant legislation, such as the Commerce Act 1986 or the Fair Trading Act 1986, and other relevant codes.

Persons lodging a complaint under this Code should refer to the administrative section of the Code. For further queries on the complaints procedure, contact Medicines New Zealand on (04) 499 4277 or email info@medicinesnz.co.nz.

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1. General Principles

- 1.1 Companies should establish and maintain appropriate protocols or standard operating procedures to ensure full compliance with this Code and to review and monitor all company promotional and other relevant non-promotional activities and materials.
- 1.2 The chief executive of a New Zealand pharmaceutical company (or, where there is no chief executive in New Zealand, the most senior manager or director in the New Zealand local operating company) is primarily responsible for ensuring adherence to the Code. Companies should ensure sufficient internal and/or external resources are available to enable adherence to this Code and should ensure that all company personnel and agents acting on the company's behalf are aware of the Code's obligations.
- 1.3 Companies must comply with the spirit as well as the letter of the Code.
- 1.4 Companies must comply with the highest ethical standards and must not misrepresent the risks and benefits of their products, or act in a manner likely to bring discredit to or reduce confidence in the pharmaceutical industry.
- 1.5 The professional status of HCPs must be considered at all times in the course of industry activities. HCPs' names or photographs must not be used by companies in a manner that would be contrary to the relevant health professional's code of conduct or professional standards.
- 1.6 Wherever a HCP's name is specified in any kind of promotional material, other than by citation of a published reference, the company must ensure that the individual specified is aware of this and provides written approval for the use of his/her name in the context of the entire promotional material, including subsequent promotional material. For example, if a doctor agrees to introduce an educational video, the doctor must be fully aware of the final content of that video, as such a situation would imply endorsement. The potential for a HCP to subsequently withdraw their approval for use of their name within any promotional material must be addressed in the pre-production agreement with the HCP.

- 1.7 All company activities (including the development and use of promotional and educational material) must conform to generally accepted standards of good taste and recognise the professional standing of the recipients.
- 1.8 Verbal communications carry the same implications as written ones, and as such must comply with the Code.
- 1.9 Company activities must not be likely to cause serious or widespread offence, taking into consideration prevailing community standards as described in the rules on decency and offensiveness in the Advertising Standards Authority (ASA) Advertising Code of Ethics.
- 1.10 This Code will be reviewed, and if necessary updated, at a minimum of every three years. Medicines New Zealand will consult with and notify all members of any changes to the Code. Companies are responsible for ensuring that all company employees and agents are complying with the current version of the Code.
- 1.11 Reference to “company”, “company employee” or “company representative” in this Code includes reference to an agent acting on the company’s behalf.

2. Legislative Requirements

- 2.1 Medicines must only be promoted for New Zealand approved indications.
- 2.2 Prior to the marketing regulatory approval process, provision of information to HCPs or the public must be limited to:
- bona fide clinical research activity from a clinical department as outlined in section 7.2;
 - the legitimate exchange of medical and scientific information (without a promotional purpose or intent) at scientific congresses or advisory boards;
 - the provision of information to policy makers responsible for healthcare planning (e.g., DHBs, Ministry of Health or PHARMAC); and
 - the provision of a response by a company's medical department to unsolicited information requests from HCPs.
- 2.4 Companies have a statutory obligation under section 41 of the Medicines Act 1981 to report adverse events associated with their medicines to Medsafe. Companies must ensure they are aware of other requirements to report adverse events to other relevant agencies such as the Standing Committee on Therapeutic Trials (SCOTT), any relevant Health and Disability Ethics Committee (HDEC), and the New Zealand Pharmacovigilance Centre (NZPhvC) including the Centre for Adverse Reaction Monitoring (CARM).
- 2.5 Companies must comply with all other relevant legislation.

3. General Advertising and Promotional Activities

This section relates to all types of advertising and promotional activities for prescription medicines regardless of the target audience.

3.1 Responsibility

3.1.1 It is the responsibility of companies, their employees and their agents to ensure that all promotional claims are fair, accurate and current. Medical claims must be consistent with the Data Sheet.

3.1.2 The responsibility in section 3.1.1 relates not only to the product being promoted, but also to any information given or claims made about other products or disease states or conditions. The obligation also applies to tag lines and their ability to be substantiated.

3.1.3 Companies should ensure that materials containing promotional claims are reviewed at least every two years to ensure they remain up to date.

3.1.4 If new product data are generated that significantly change the safety or efficacy profiles of a product all promotional material for that product must be reviewed and either revised or withdrawn.

3.2 General Advertising Requirements

3.2.1 Advertisements and promotional material must comply with all relevant New Zealand legislation and codes of practice.

3.2.2 All advertising and promotional material (excluding Brand Name Reminders, see section 4.1.4) must be pre-vetted and approved by an Association of New Zealand Advertisers (ANZA) approved process, such as the Therapeutic Advertising Pre-vetting System (TAPS). This process includes review of the material by the TAPS adjudicator and/or TAPS Delegated Authority (TAPS DA).

3.2.3 Advertisements and promotional material should be in good taste and must not bring the pharmaceutical industry or HCPs into disrepute.

3.2.4 Material relating to medicines and their uses, whether promotional in nature or not, which is sponsored by a company, should clearly indicate by whom it has been sponsored. Advertising and promotional activities must not be deliberately disguised (see section 4.3).

3.2.5 The type size and graphics used in all advertisements and promotional material should be clear, legible and easily understood by the intended audience. The type size should be not less than 1.5mm, as measured by the height of the font's lower case "e" and should appear on a background sufficiently contrasting for legibility.

3.2.6 Advertisements and promotional material should provide balanced information on the benefits and risks of the product.

3.2.7 Advertisements and promotional material should not by implication, omission, ambiguity or exaggerated claim mislead or deceive, or be likely to mislead or deceive, consumers or HCPs, abuse the trust of or exploit the lack of knowledge of consumers or HCPs, exploit the superstitious, or without justifiable reason, play on fear.

3.2.8 Advertisements and promotional material should not imitate the devices, copy slogans, or general layout adopted by other companies in a way that is likely to mislead or confuse.

3.2.9 Advertisements and promotional material should not have depictions that unduly glamorise the product or portray unrealistic outcomes.

3.2.10 Therapeutic claims must be factual and adequately referenced. All scientific information in an advertisement or promotional item must be accurately presented. Scientific terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed.

3.2.11 Advertisements for Class A, B, and C controlled drugs as defined in the Misuse of Drugs Act 1975 must be directed at HCPs only and in appropriate media.

3.3 Promotional Claims

3.3.1 Exaggerated or all-embracing promotional claims must not be made and unqualified superlatives must not be used. Promotional claims should not imply that a medical product,

or an active ingredient, has some special merit, quality or property, unless this can be substantiated and is referenced.

Use of the definite article to imply a special merit, quality or property for a medicine is unacceptable. For example, a claim that a product is “The analgesic” implies that it is in effect the best, and would not be acceptable.

3.3.2 All promotional claims must be current, accurate, be capable of substantiation and must not be misleading either directly, by implication, by scale or by omission. Graphics should not be used in any way which might mislead; for example, by their incompleteness or by the use of suppressed zeros or unusual scales.

3.3.3 Promotional claims must be based on an up-to-date evaluation of all relevant scientific evidence and should clearly reflect the balance of such scientific evidence. Any information used to support a promotional claim that is not contained in the Data Sheet must include sufficient detail and be of adequate quality to allow evaluation of the results. This information should not be based solely on the findings of a single paper or study unless that paper fairly represents the balance of current scientific evidence.

3.3.4 All promotional claims must be clearly referenced. References cited in promotional material must be made available within 10 working days of receipt of a written request.

3.3.5 “In vitro” or “laboratory tests” and “trials in animals” are not sufficient to substantiate a promotional claim. In vitro or animal models can only generate a hypothesis that the product may have some effect in humans. The limitations of extrapolating these data to humans must be made clear.

3.3.6 Any statement about adverse effects should be specific and consistent with the Data Sheet and may be supported by published data to which references are given. It must not be stated that a product has no side-effects, toxic hazards or risks of addiction or dependency. Companies are encouraged not to use the word "safe", "safely", "safety" or "safer" without qualification. A balanced reference to the product's tolerability is preferred.

3.4 Comparisons

3.4.1 Comparisons must be made on a factual and fair basis and be capable of substantiation in accordance with the balance of medical evidence.

3.4.2 Comparisons must not mislead by distortion, by undue emphasis, or in any other way. “Hanging” comparatives - those that claim a product is better, stronger, or more widely prescribed, must not be used.

3.4.3 Where a claim of comparative efficacy or safety is made, it must not be based solely on a comparison of product Data Sheets, as the clinical trial data used for registration purposes are not directly comparable between products unless head-to-head studies have been carried out. Comparative claims must be scientifically valid and appropriately referenced.

3.4.4 Product comparisons should not be used in Direct to Consumer Advertising (DTCA) (see section 5.11).

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

- the lack of significance must be stated explicitly; it is insufficient to state only the p value;
- the statement that the claim is not statistically significant needs to be linked to the original claim, made on the same page and within a reasonable proximity of the original claim in a manner that is not obscured by other material; and
- the data must not be used to generalise or to indicate superiority or inferiority.

3.5 Data on File

Promotional claims should not rely exclusively on data on file unless such data are part of the approved registration package.

3.6 Disparaging References

The products or services of other pharmaceutical companies and the clinical and scientific opinions of HCPs must not be insulted or subject to unreasonable or unfair criticism either directly or by implication. Objective or scientific comment is acceptable.

3.7 Personal Communication

Where the views of individual clinicians are used in promotional claims to HCPs, they should be balanced, fair, and consistent with current scientific evidence (see sections 3.8, 3.11).

3.8 Quotations

3.8.1 Quotations relating to prescription products taken from unpublished public broadcasts, conferences or symposia must not be used in promotional material without the presenter's written permission (unless the content is subsequently published, and can thus be referenced to the published article). Care should also be taken to avoid ascribing unpublished claims or views relating to prescription products to a presenter when such claims or views no longer represent, or may not represent, the current view of that person.

3.8.2 When a company publishes quotations from a HCP from previously unpublished public broadcasts, conferences or symposia into a company promotional piece (which must be with the HCP's written consent), the company alone is responsible for the content of the promotional piece. The promotional material must comply with all relevant sections of this Code.

3.8.3 Company promotional material directed at HCPs may contain brief quotations from a HCP that appear in a published article and reference the HCP's name. Quotations must not change or distort the HCP's original meaning as expressed in such published article and must reflect the meaning of the entire article and the author's current opinion.

3.8.4 Quotations from medical and scientific literature must otherwise be accurately reproduced and the precise sources identified. The intended meaning of the author or clinical investigator, or the significance of the underlying work, must be accurately conveyed.

3.8.5 Quotations from personal communication must be properly referenced, reflect the meaning of the author and, where appropriate, state the statistical significance of the study.

3.9 "New" claim

3.9.1 The word "new" should not be used to describe any product or specific formulation that has been available to be prescribed and supplied for more than twelve months in New Zealand, or any therapeutic indication that has been promoted for more than twelve months in New Zealand.

3.10 Endorsements

3.10.1 Advertisements and promotional material must not claim or imply endorsement by any government agency, professional body or independent agency unless there is prior consent, the endorsement is verifiable, the agency or body is named and the endorsement is not otherwise prohibited by law.

3.10.2 Advertisements cannot include any statement indicating that the Medicines Assessment Advisory Committee or the Medicines Adverse Reactions Committee, or a member of either committee, or an officer of the Government has approved or refrained from disapproving the advertisement or any of the claims or statements made in it (refer Medicines Regulations 1984, regulation 7).

3.10.3 Companies must not include anything in a promotional claim that states or implies that consent to distribution for the product by Medsafe amounts to endorsement of the product by Medsafe or any other Government agency. No reference may be made to the consent to distribution in any label or advertising, promotional or other published material about the product.

3.10.4 Where reference is made to the prescribing of a preparation in terms of the Pharmaceutical Schedule, the phrase "freely prescribed on the Pharmaceutical Schedule" and similar misleading phrases must not be used. Companies must not state or imply to a doctor or a patient that a product which is not currently listed on the Pharmaceutical Schedule will be listed on the Pharmaceutical Schedule in the future or will attract any other form of Government subsidy.

3.10.5 Promotional material to HCPs or to consumers (i.e. DTCA) must not intimate or imply endorsement by any appropriate professional body or patient advocacy group without the prior written consent of that body or group and the endorsement must otherwise be lawful. A copy of the consent must be made available on request and must be appropriately referenced in any advertisements or promotional material.

3.10.6 DTCA must not directly or by implication claim, indicate, or suggest that a medicine is or has been used, recommended, or endorsed by a HCP (including the use of an actor portraying a HCP) or by a celebrity.

3.10.7 If the name or testimonial of a HCP is used in advertisements or promotional material to other HCPs, other than by citing published references, the HCP's written approval must be obtained and made available upon request. Care must always be taken to ensure that the representation of the HCP's views is accurate, balanced, fair, and up to date.

3.11 Testimonials

3.11.1 Patient testimonials (e.g. the presentation of patient case studies) are prohibited in DTCA.

3.11.2 Use of patient testimonials in advertising and promotion to HCPs must represent views that are scientifically valid, true, current and typical. Patient testimonials must also be verifiable and documented.

3.12 Electronic Media Promotion

3.12.1 Medicines New Zealand supports the right of member companies to use the internet as a means of advertising and providing accurate and scientifically reliable information on medicines, in a responsible manner, for the benefit of both patients and HCPs. This section applies to any electronic or audio-visual media designed by companies to promote their products, including (but not limited to):

- the internet;
- company websites;
- company controlled websites;
- smart phone applications;
- mobile device software and applications;
- podcasts & webcasts;
- electronic mail (including email, text messages and eNewsletters);
- software programmes used by company representatives during interactions with HCPs;
- material for individual use by HCPs or consumers;
- material for demonstration purposes to an individual or group(s) of HCPs including DVDs and USBs; and
- advertisements in such programmes as prescribing and dispensing software.

3.12.2 All material in electronic media that promotes prescription medicines must comply with relevant legislation and codes, (including the ASA Therapeutic Products Advertising Code) and the sections of this Code that are relevant to the nature of the promotional material and target audience.

3.12.3 Any references or links to other information sources or internet sites about a company's prescription medicines must be to reputable sources that provide valuable educational material that would enhance the quality use of those prescription medicines in New Zealand and be easily understood by the target audience. Companies must take all reasonable steps to ensure that these sources comply with the requirements of this Code and relevant legislation, and are consistent with the relevant Data Sheet. Companies must not knowingly refer customers to product sites where the content does not comply with NZ legislation and advertising codes.

3.12.4 Where references are made to other information sources or internet sites, including non-product websites of company subsidiaries in another jurisdiction, companies must take all reasonable steps to ensure that these information sources and internet sites are appropriate and will enhance the quality use of prescription medicines in New Zealand. Websites that promote a subsidiary company in another jurisdiction rather than its products will not be considered to contain 'advertisements for a medicine' unless direct, or in some cases indirect references, are made to the company's products. It must be made clear when readers click on an embedded link or similar, taking them to a website in another jurisdiction, that the reader is leaving the local NZ company website to another site that the local company has not developed and which may not be consistent with New Zealand legislation or advertising codes. The links (or similar) should not appear on the product page(s) unless the information on those pages complies with the requirements of this Code and relevant legislation, and are consistent with the Data Sheet (see section 3.12.3).

3.12.5 Unsolicited email transmissions are prohibited by law and must not be used for promotional purposes.

3.13 Electronic Media Promotion to HCPs

3.13.1 All electronic promotional material that is only accessible to HCPs must comply with the requirements for a Full or Short Advertisement, as appropriate.

3.13.2 Information provided on the internet or via mobile media platforms or Applications (Apps) and intended only for use by HCPs must be accessible only via a secure system that is designed to prevent access by members of the general public. The intended audience should be readily apparent from the information contained on the site.

3.13.3 A list of substantiating references must be provided in electronic promotional material whenever a promotional claim is made.

3.13.4 All electronic detail aids must meet the requirements of this Code and relevant legislation. Care should be taken to ensure that all text on electronic detail aids is easily legible from a comfortable distance, and that the information on each page is not false or misleading when read in isolation. Placement of mandatory requirements (e.g. generic names, p-values, etc) or qualifying statements to claims, should be clearly visible on screen, and cannot only be visible within an animated feature such as a pop-up.

3.13.5 Mobile media platforms, Apps and QR Codes - A company may wish to provide promotional and educational material to HCPs via an application downloaded on mobile media platforms (e.g. iPhone and iPad; Blackberry; Android based smart phones and other tablets) or via a QR code which links directly to an application or microsite. Such applications must be accessible via a secure application (e.g. password protected) that is designed to allow access only to HCPs. Any product advertising must comply with the relevant sections of this Code.

3.13.6 Branded web banner advertisements directed at HCPs must comply with the requirements for a short advertisement.

3.14 Electronic Media Promotion to Consumers

3.14.1 When product-specific websites are accessible to the general public, they are deemed DTCA. They must comply with the DTCA sections of this Code, and must provide the CMI of the promoted product, or link directly to the CMI on the Medsafe website.

3.14.2 Product related pages on company websites based in NZ must include a TAPS approval number (non-product content is the responsibility of the company and does not require TAPS review) and the date of last update on the homepage.

3.14.3 Websites accessible to the general public must state that any information provided on the website should be discussed with a HCP, and does not replace a HCP's advice.

3.14.4 Companies should have a process for managing enquiries from company websites to ensure compliance with the Code. Requests from individual members of the public for personal advice on the diagnosis of disease or choice of therapy must always be politely refused and such individuals must be advised to consult their HCP.

3.14.5 Online advertisements must comply with relevant legislation, other codes and the sections of this Code that are relevant considering the nature of the promotional material and target audience. Mandatory information may be broken up into sections if using revolving screens or 'read more' hover screens.

3.14.6 Online advertisements may use linked pages on a company's website that together constitute the entire advertisement. In such cases:

- the first screen of the advertisement must include, at a minimum, the mandatory information required in section 5.11.10 of this Code.
- there must be a statement on the first screen of the online advertisement that readers can access the further information required in section 5.11.11 of this Code by clicking on a link appearing on the front page.
- the first screen may also link through to promotional and/or therapeutic claims.

3.14.7 Unbranded banner advertisements are permitted where the purpose is to attract viewers through to a branded site. Banners must not "advertise by stealth" (i.e. make specific product claims without mentioning the brand name) or use imagery that is well recognized by the target audience as being "the brand".

3.14.8 Company websites may contain clinical information that is useful to the general public. All information provided to members of the general public about prescription medicines on New Zealand based websites must be consistent with the product's current Data Sheet.

3.14.9 Offers on a New Zealand originated company website should state that the offer only applies to New Zealand residents.

3.14.10 Competitions directed at consumers are prohibited.

3.14.11 Where company websites solicit personal consumer information through orders, membership of clubs and subscription to general newsletter follow-up, the requirements of the Privacy Act 1993 must be met. Such websites must contain a privacy statement in accordance with requirements of the Privacy Act similar to: “Note: Your personal information will be kept confidential and not distributed to third parties. You have the right to inspect, change or delete this information. Your information will be used solely for the purposes of xxx ”

3.15 Social Media

3.15.1 Social media means any form of online channel, providing the potential for a two way interaction between two parties (and may be directed at either HCPs or the general public). Social media includes (but is not limited to) Facebook, YouTube, MySpace, Twitter, Wikis, LinkedIn. Advertisements or information intended for distribution via social media are considered advertising and therefore must comply with the relevant sections of this Code and legislation. Owned, paid-for, or sponsored content on social media sites would be considered advertising by the company and must comply with the requirements of this Code and relevant legislation.

3.15.2 Companies are responsible for all content and activities on interactive company-owned social media sites where their prescription medicine products are discussed.

3.15.3 User generated content that a company chooses to keep on a site, or extracts from one site and places on another site, is the responsibility of the company and must be held in accordance with relevant laws.

3.15.4 Companies must comply with the requirements of Code and not post:

- content which does not conform to community standards of ethics and good taste;
- content which relates to unregistered products or indications;

- content which is inappropriate;
- content which may be considered false or misleading; and
- content which may represent a patient testimonial or HCP endorsement.

User-generated posts that do not comply with the above should be removed as soon as discovered (or at least within 24 hours) of posting.

3.15.5 Any activity on a social media site by a company employee, or the employee of an agency acting on the company's behalf in relation to prescription medicines, must comply with this Code. Employees or agents who are active on a social media site and who are there on behalf of the company must identify themselves as such.

3.15.6 If using paid for Twitter endorsements, use of the hash tag #ad is required. Care should be taken to ensure the endorsement is not a patient testimonial or a HCP endorsement to the public, both of which are prohibited by the Medicines Act. Wherever practical within the context of the conversation, consumers should be reminded to "talk to your doctor".

3.15.7 All adverse events relating to a company's prescription products described on company-owned sites reported or identified by users must be reported to the relevant regulatory agency by the company in accordance with legislative requirements. Adverse events relating to a company's products discovered on third-party sites, either by a company or its agent must also be reported as above.

3.15.8 TAPS or TAPS DA approval must be sought for the outline and static content of the social media page.

3.16 Events/programme Sponsorship Advertising

3.16.1 Any product-related sponsorship advertisements directed at the public must comply with the DTCA requirements in this Code.

3.16.2 Any product-related sponsorship advertisements directed solely at HCPs must comply with the requirements for advertisements to HCPs in this Code.

4. Activities Directed at HCPs

4.1 Advertisements to HCPs

4.1.1 Advertisements to HCPs

All advertisements and promotional material should include a clear and prominent statement drawing the attention of the reader to any restriction or non-availability of a medicine via the Pharmaceutical Schedule. The disclosure of this information must accurately reflect the approval and Pharmaceutical Schedule listing but may be a paraphrase or précis of that information.

4.1.2 Full Advertisements

4.1.2.1 A full advertisement is any advertisement that includes a therapeutic or promotional claim.

4.1.2.2 A full advertisement must contain the following within the body of the advertisement:

- (a) The brand name of the product.
- (b) The New Zealand Approved Name(s), usually INN, of the active ingredient(s).
- (c) The quantities of the active ingredients in the medicine.
- (d) The name of the sponsor and the locality of the registered office.
- (e) The medicine classification.
- (f) The approved indication(s) of relevance to the advertisement.
- (g) Contra-indications to the use of the product.*
- (h) Common and serious adverse events associated with the use of the product.
- (i) Appropriate precautions for the use of the product.*
- (j) Information on the effectiveness and limitations of the medicines.
- (k) Where relevant, restrictions on distribution±.
- (l) Dosage regimen and mode of administration, or method of use.
- (m) A clear statement regarding the funding status of the product or any restrictions to the Pharmaceutical Schedule listing. Examples include:

- X is an unfunded medicine – a prescription charge will apply;
- X is a partially funded medicine – a prescription charge will apply;
- X is a funded medicine – restrictions apply.

(The source of any funding restrictions, e.g. the Pharmaceutical Schedule, should be properly noted in the references of the promotional piece).

(n) A clear statement directing the prescriber to review the Data Sheet before prescribing the medicine.

(o) Reference to where the Data Sheet is immediately accessible.

(p) The TAPS or TAPS DA approval number.

****As a minimum, the most important information in these categories should be included.***

± An example of where this applies is where a product is only available via certain prescribers or from certain pharmacies or outlets.

4.1.2.3 Care should be taken to ensure that any items in a pack or set of materials (including covers) that contain promotional claims, comply with the requirements for promotional materials in 4.1.2.2.

4.1.3 Short Advertisement

4.1.3.1 A short advertisement is designed to remind a prescriber of a product's existence but must not contain therapeutic or promotional claims.

4.1.3.2 A short advertisement must contain:

- a) The medicine classification.
- b) The approved indication(s) of relevance to the advertisement.
- c) Appropriate precautions for the use of the product.
- d) The TAPS or TAPS DA approval number.
- e) The brand name of the product.
- f) The New Zealand Approved Name(s), usually INN, of the active ingredient(s).
- g) The name of the sponsor and the locality of the registered office.
- h) A clear statement directing the prescriber to review the Data Sheet before prescribing the medicine.
- i) Reference to where the Data Sheet is immediately accessible.

A short advertisement may also contain:

- j) A statement of available dosage forms.
- k) Graphics of a non-promotional nature.
- l) Details of the reimbursement status of a medicine.
- m) A statement that further information is available from the company.
- n) The company URL.

4.1.4 Brand Name Reminder (BNR) Items

4.1.4.1 An individual BNR Item should only be of token value (not likely to be greater than NZ\$20.00 per item (excl GST). BNR Items should not bring discredit to the industry and should be chosen on the basis that the item is clearly a BNR and not any other form of promotional material. The nature of any BNR Item or its packaging must not have the capacity to be confused with a therapeutic product. BNR items do not need TAPS or TAPS DA approval.

4.1.4.2 BNR Items must have some relevance to the practice of the relevant HCP. Items that are more likely to be regarded as being for use in the home, or for recreational activities, are prohibited.

4.1.4.3 BNR Items must:

- a) Be inscribed with the Brand and approved name (usually the INN) and company name or logo.
- b) Not contain any promotional claims, including promotional tag lines and/or statements.
- c) Be directed only to HCPs.
- d) Not contain any other information, e.g. therapeutic class, approved use(s).

4.2 Medical Literature and Reprints

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

4.2.1 The interpretation and conclusions of any reprints of journal articles, proceedings of educational events or summaries of literature used in promotion must be consistent with the Data Sheet.

4.2.2 Reprints must be used in a fair and balanced manner. No part of the reprint or article should be specifically highlighted to draw the attention of a HCP. Reprints must not be abbreviated, over-stickered, underlined, or otherwise modified.

4.2.3 Reprints themselves do not need to be accompanied by the Data Sheet, but any accompanying material (including covering letters) or presentation made that incorporates promotional claims must comply with the requirements of this Code (see section 4.1.2).

4.2.4 Companies must not promote the use of unapproved indications or products to HCPs. HCPs may request literature on unapproved products or subjects not covered by the Data Sheet, such as unapproved indications. Such information may be supplied by a company to a HCP if the HCP makes an unsolicited request, provided that the literature or accompanying communication clearly identifies that it refers to a product or indication not approved in New Zealand. If the product is approved in New Zealand, it must be accompanied by the Data Sheet, or the response must direct the HCP to the Data Sheet on the Medsafe website. Information provided on unapproved products or indications in response to an unsolicited request by a HCP must not be promotional and should be distributed by the company's medical department. Information on unapproved products or indications must not be provided to HCPs in the absence of an unsolicited request from the HCP, as this would be considered promotion.

4.3 Company-commissioned Articles/Reports (Advertorials), and sponsored information material

4.3.1 Material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that company. See 4.3.6 for declaration of sponsorship.

4.3.2 Articles or supplements (e.g. product reviews and/or disease area overviews and/or conference reports) are promotional material under the Code if the company had any influence over the content (e.g. by choosing the author; commenting on a draft of the manuscript).

4.3.3 Company commissioned articles should not resemble independent editorial matter. Company commissioned articles are medical advertisements as defined under the Medicines Act 1981 and must meet the requirements of this Code. Waivers or disclaimers will not abrogate a company's responsibility if the material includes reference to off-label use of a product.

4.3.4 Promotional claims must also comply with this Code.

4.3.5 Nothing in this section is intended to include technical, medical or scientific articles resulting from company-sponsored clinical trials. Authors of such articles should comply with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals or similar.

4.3.6 The company responsible for commissioning or sponsoring the material must be clearly identified. Companies must also make clear the extent of their involvement in the production of any of the material by adding an appropriate disclosure statement(s) to the piece. Such statements should be clearly identified at the top of the article, in a type of not less than 2mm as measured by the height of the lower case "e".

4.3.7 Statements by third parties that are quoted in company commissioned articles, must comply with Sections 2 and 3 of this Code.

4.4 Reference Manual Advertising

Advertisements in reference manuals (e.g. MIMS New Ethicals, eMIMS) must comply with the relevant sections of this Code. In the event that the reference manual does not provide the Data Sheet, direction must be given in the body of the advertisement as to where this information can be obtained (e.g. by directing the reader to the Medsafe website or to contact the company).

4.5 Mailings (including Electronic Mail)

4.5.1 Mailings, including those that make promotional claims, must comply with all relevant sections of this Code.

4.5.2 Mailings must only be sent to those categories of HCPs that have a need for, or interest in, the particular information.

4.5.3 Mailing lists must be kept up to date.

4.5.4 Requests by HCPs to be removed from promotional mailing lists must be complied with promptly and no name restored except at specific request or with written permission of the HCP.

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

4.5.6 The display of a product's brand name and logotype, NZ Approved Name and INN name alone on mailings directed towards HCPs is not considered as promotion to the general public in this context. Within this context however, taglines are not allowed.

4.5.7 Statements on envelopes implying urgent attention must be restricted to matters relating to product recalls or important safety information.

4.5.8 Envelopes must not be used for dispatch of promotional material if they bear words implying that the contents are non-promotional.

4.5.9 Any accompanying material sent with a mailing must comply with the requirements of this Code as a stand-alone item.

4.6 Professional Trade Displays

4.6.1 Professional trade displays must be directed only to HCPs.

4.6.2 A professional trade display must include the name of the sponsoring company.

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

4.6.4 All promotional material used at a professional trade display must comply with the requirements of this Code. The products/indications being promoted must have approval in New Zealand.

4.6.5 Banner advertisements exhibited at professional trade displays must:

- a) Include the brand name of the product.
- b) Include the New Zealand Approved Name(s), usually the INN, of the active ingredient(s).
- c) Include the name or logo of the sponsor and the locality of the registered office.
- d) Include the TAPS or TAPS DA approval number.
- e) Not contain any promotional claims, including promotional tag lines and/or statements (except as in 'iii' below).

Banner advertisements exhibited at professional trade displays may also:

- i. Have a brief statement of the approved uses (indication(s)).
- ii. Include the company address.
- iii. Include additional information so as to comply with the requirements of a full advertisement or a short advertisement as outlined in this Code.

4.6.6 The Data Sheet for products being promoted must be available from the professional trade display stand.

4.6.7 Sample/starter packs must not be made available for collection from professional trade display stands.

4.6.8 Sample/starter packs for products not approved for marketing in NZ must not be provided.

4.6.9 Competitions that are held as part of a professional trade display must be consistent with the requirements of this Code.

4.6.10 To encourage HCPs to attend a professional trade display, a company may offer BNR Items.

4.6.11 Gifts, cash payments and/or donations to charities or societies must not be offered to HCPs as an incentive to visit professional trade display stands.

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

4.7 Interactions and Relationships with HCPs

4.7.1 The primary objective for any interaction with HCPs must be to improve patient care in New Zealand by increasing medical knowledge and enhancing the quality use of medicines.

4.7.2 Relationships with HCPs must be able to withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste. No benefits, financial or otherwise, may be provided on condition that HCPs recommend, prescribe, or use a prescription medicine.

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

4.7.4 Payment for access to HCPs is prohibited.

4.8 Company Organised Meetings – General Principles

4.8.1 Venues

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

4.8.1.2 The venue, location, and environment at which a company provides hospitality to HCPs must be conducive to education and learning. The choice of venue must be able to successfully withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste.

4.8.1.3 Appropriate venues for company educational meetings would be conference centres, meeting facilities in a city/suburban hotel, or a rural equivalent. The venue must not be chosen for its leisure, sporting or recreational facilities so as to minimise any disruption of the educational activity(ies) conducted.

4.8.1.4 If the educational meeting requires “hands-on” training in medical procedures, it should be held at a training facility, medical institution, or other appropriate facility (for example, a medical practice or hospital). In this instance, companies may provide payment to a medical institution or other facility, such as medical practice or hospital, to cover the direct costs for the use of the facility for the educational meeting. Any such payment must be commensurate with the actual cost to the medical practice or institution for making their facility available for the meeting, and must not constitute payment for access to the health professionals at that facility.

4.8.2 Hospitality

4.8.2.1 The provision of hospitality in the absence of medical/scientific education is prohibited.

4.8.2.2 Any hospitality provided by a company must be clearly secondary to the educational purpose of the meeting. Meals and beverages must be appropriate for the educational content and duration of the meeting and should not be excessive.

4.8.2.3 Offering “takeaway” meals or meals intended to be eaten outside the meeting (such as “dine and dash” programmes) are prohibited.

4.8.3 Entertainment

4.8.3.1 Interactions between companies and HCPs must not include entertainment.

4.8.3.2 Companies are prohibited from organising meetings directly associated with any entertainment or recreational activity. Such events must not be paid for, or facilitated, by the company. An example of this would be to include an invitation to an educational meeting with advertisements for any entertainment or recreational activity.

4.8.4 Travel and Accommodation

4.8.4.1 Travel may be provided to delegates of a company organised meeting only if the meeting content is related to the HCP’s area of expertise and the origin of the delegate justifies reimbursement. Land travel costs can be reimbursed against the presentation of receipts (train, bus, taxi) or in the case of private vehicle, the IRD-recommended petrol rate multiplied by the number of kilometres travelled.

4.8.4.2 Flights must be booked directly by the sponsoring company(ies) to prevent the exchange of tickets to benefit another individual (e.g. trading in a business class ticket for two economy class tickets to allow a spouse or partner to accompany the traveller). Alternatively, reimbursement can be made for flights when the sponsor is contributing towards the costs of associated travel and that travel cannot reasonably be booked directly by the company. Reimbursement can only be made on presentation of bona-fide receipts as anticipated in a prior contractual agreement. Travel for HCPs must be by economy class within New Zealand. Business class travel is only acceptable for an international flight time that exceeds 5 hours duration. First class travel for international flights is prohibited.

4.8.4.3 A reasonable level of accommodation expenses may be provided to delegates. The number of nights’ accommodation should be determined by the meeting agenda. Accommodation should not to be provided for single calendar day meetings unless the attendees travel schedule does not allow them to arrive by the start of the meeting or does not allow them to depart on the day the meeting concludes. The location of the

accommodation should be within easy access of the meeting venue, should be appropriate to the occasion, and should conform to standards of ethics and good taste.

4.8.4.4 A company must not subsidise or pay for any additional travel, accommodation, or other expenses not directly related to the conference or for any accompanying persons.

4.8.5 Speakers

Companies organising (whether this involves payment or not) a HCP to speak at a company-organised meeting must ensure, as a condition of the contract that the HCP is familiar with the approved indications for the relevant product(s) and is aware of the obligation not to promote unapproved medicines or indications. Companies must be able to provide documentary evidence of this briefing and its contents, which can be publicly disclosed if required.

- a) This applies irrespective of whether the company has provided the HCP with a presentation or other material.
- b) This does not apply to independent third-party educational events or company-sponsored external meetings where an independent scientific faculty has chosen the topics and speakers.

4.8.6 Guests

Invitation of a HCP's partner or other guests is prohibited unless the partner or guest is also a HCP and would have been invited in their own right.

4.9 External Meeting Sponsorship and/or Support

4.9.1 General principles

4.9.1.1 Companies may sponsor or provide administrative support to education meetings organised by a third-party such as a society, college, university or other HCP organisation if the primary objective of any sponsorship or support is to enhance the medical knowledge and the quality use of prescription medicines in New Zealand.

4.9.1.2 Companies must be fully aware of the activities that any sponsorship will support and be satisfied that they are able to withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste.

4.9.1.3 Financial sponsorship of any educational meeting should be paid to the third-party or HCP organisation and not paid directly to any individual HCP.

4.9.1.4 Companies must develop clear guidelines and ensure contracted agreements are in place to outline the extent and parameters of the sponsorship/support. No sponsorship should be conditional upon any obligation to prescribe or recommend a particular product. Sponsorship must not interfere with the independence of a HCPs prescribing or dispensing practices.

4.9.2 Educational Content

4.9.2.1 The external third-party organising the educational meeting should independently determine the agenda and educational content, select the speakers, and invite the attendees. A company may propose a speaker for the meeting, but the final choice of speakers will be determined by the third-party organiser.

4.9.2.2 Objective evidence of the educational value of the educational meeting is required (for example an agenda or scientific programme) that clearly describes the educational purpose, content, meeting start and finish times, and duration of the educational session(s). Companies should undertake a review of the educational value prior to agreeing to sponsor the meeting.

4.9.2.3 A company may choose to sponsor an in-institutional meeting (for example, journal club, grand round, multidisciplinary or in-service meetings) held within a HCP workplace. Sponsorship should only be offered if the primary purpose of the meeting is to provide medical education.

4.9.3 Venue, Hospitality, and Entertainment

4.9.3.1 Companies must critically examine the proposed venue and any hospitality of a sponsored educational meeting.

4.9.3.2 The venue should have the facilities to support the provision of education (for example, private room with audio-visual facilities). The same principles that apply for company organised events in section 4.8.1 apply to events sponsored and/or supported by companies.

4.9.3.3 Hospitality provided at the sponsored meeting must be appropriate for the educational content and duration of the meeting, and is secondary to the educational content.

4.9.3.4 Interactions between companies and HCPs must not include entertainment and companies must not pay for or sponsor entertainment delivered by a third party.

4.9.3.5 A company must not pay for hospitality, travel, or other expenses of any guest, family or companion.

4.9.4 Travel and Accommodation

4.9.4.1 The same principles that apply for company organised events in section 4.8.4 apply to events sponsored and/or supported by companies.

4.9.5 Remuneration

4.9.5.1 Delegates must not be paid for attendance at sponsored educational meetings.

4.9.5.2 Any remuneration paid to a speaker or chair must be commensurate with the work involved and should be formally documented and agreed between the sponsoring company and the individual HCP or meeting organiser (see section 4.15).

4.9.6 Disclosure

4.9.6.1 When meetings are sponsored or supported by companies, this fact must be disclosed. There must be a prominent declaration of sponsorship/support at the meeting, outlining the role and extent of support, of the company.

4.9.6.2 Materials produced subsequent to the meeting by the company, must also prominently declare such disclosure and comply with the requirements of this Code.

4.10 Competitions

4.10.1 Promotional competitions for HCPs must fulfil all of the following criteria:

- a) The competition is based entirely on medical knowledge or the acquisition of medical knowledge.
- b) The prize is: i) an item of educational value (for example, but not limited to, a medical textbook or the enrolment fee paid to attend a medical/health-

related conference), or ii) directly relevant to the practice of medicine or pharmacy and is intended for use in a surgery, hospital or pharmacy.

- c) Individual prizes offered are to be of a moderate monetary value (taking into account the number of participants and prizes – i.e. the larger the number of prizes the smaller the monetary value each prize must have).
- d) There must be appropriately documented processes for determining the winner/s of a competition, which requires that answers are correct and does not rely solely on chance to determine the ultimate winner(s).
- e) Competitions must also comply with any relevant legislation.

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

4.11 Gifts and Offers

4.11.1 The provision of gifts and offers to HCPs is prohibited unless they meet the requirements of:

- a) BNR Items
- b) Company-branded items of stationery
- c) Educational material directed to HCPs or patients
- d) A prize for a complying competition
- e) Sponsorship to attend an educational event
- f) Hospitality at an educational event

4.11.2 No gift, benefit in kind, or pecuniary advantage shall be offered or given to HCPs as an inducement to recommend, prescribe, dispense or administer a company's product(s).

4.11.3 Since cash or equivalent payments of any kind can create a potential appearance of impropriety or conflict of interest, payments in cash or cash equivalents (such as gift certificates) shall not be offered to HCPs either directly or indirectly.

4.12 Donations of Items of Medical Utility

4.12.1 Provision of items of medical utility by companies to medical or allied health associations, hospitals, departments, or private health practices should only be considered if the item will improve the quality use of medicines. Items of medical utility cannot be donated to support routine business activities or expenditure.

4.12.2 Items of medical utility may include medical equipment and items related to the delivery of health care to patients, such as, but not limited to:

- nebulisers;
- sphygmomanometers;
- weighing scales; and
- X-ray light boards.

4.12.3 All donated items of medical utility should bear at least the company name.

4.12.4 The offer or donation of items of medical utility must not be conditional upon any obligation to prescribe a particular product, or be offered or provided in a manner or on conditions that would interfere with the independence of a HCP's prescribing or dispensing practices.

4.13 Grants

4.13.1 The Code of Practice recognises the significant contribution of the pharmaceutical industry to the quality use of medicines in New Zealand through financial support of HCP activities.

A company may provide a grant or financial support only to a HCP, medical practice, hospital, institution or health related organisation for the following purposes:

- a) education, training or academic purposes; or
- b) medical research; or
- c) activities that improve the quality use of medicines or improve patient outcomes e.g. a clinical audit programme.

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

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

- a) There must be a documented contractual agreement outlining the nature of the

grant or financial support provided.

- b) Grants cannot be made to support educational activities of a business nature, nor for expected business expenditure (e.g. computer software training, etc.).

4.14 Non-Healthcare Organisation Sponsorship

4.14.1 Corporate sponsorship can be provided by a company to organisations that support cultural, educational, philanthropic, sporting and artistic activities or charities.

4.14.2 Companies should ensure that sponsorship activities comply with the highest ethical standards and do not bring the pharmaceutical industry into disrepute.

4.14.3 If sponsorship is for promotional purposes then such activities must comply with the requirements for DTCA as outlined in this Code.

4.14.4 Sponsorship provided to patient organisations must also comply with the requirements outlined in Section 5 of the Code.

4.15 Consulting Arrangements with HCPs (e.g. Advisory Boards)

4.15.1 Companies may legitimately seek the services of suitably qualified and experienced HCPs to provide service, advice and or guidance on a range of matters. Compensation, not exceeding fair market value, and reimbursement of reasonable travel, accommodation and meal expenses incurred as part of providing those services may be paid to the consulting HCP on presentation of bona-fide receipts as outlined in a contractual agreement. Interactions between companies and consultants must not include entertainment or recreation. Consultant arrangements, including membership of Advisory Boards, must meet all the following criteria.

- A legitimate need for the services has been clearly identified and documented in advance of requesting the services and entering into arrangements with the prospective consultants.
- There must be a written contractual agreement, outlining the purpose and objectives of the interaction and the nature and duration of the services to be provided.

- Any remuneration for services rendered must be based on fair market value and should not exceed that which is commensurate with the services supplied. The remuneration amount should be outlined in the contractual agreement.
- The number of HCPs retained as consultants or members of the Advisory Board must not exceed the number reasonably necessary to achieve the identified purpose.
- The nature of the Advisory Board must be such that it would withstand public and professional scrutiny and the purpose must be to enhance the quality use of prescription medicines.
- The venue and circumstances of any meeting with consultants should be conducive to the consulting services, and activities related to the services should be the primary focus of the meeting.

4.15.2 The purpose, objectives, and justification of the size/number of advisory boards and advisory board members must be documented prospectively. It must be made available for scrutiny in the event of a Code complaint.

4.16 Sponsorship of HCPs to Attend Medical Educational Meetings

4.16.1 The Code recognises the fact that HCP-association conferences, continuing medical education (CME) or other third-party educational meetings can contribute to the improvement of patient care in New Zealand and therefore, financial support from companies to assist HCPs with attendance at such conferences or meetings is permissible, provided that:

- i) The core scientific agenda and core content of the conference or meeting is organised and conducted independently of the sponsoring company(ies);
- ii) Sponsorship to attend the conference or meeting is not conditional upon any obligation to prescribe a particular product, i.e. nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a HCP's prescribing or dispensing practices;
- iii) The conference or meeting is directly related to the HCP's area of expertise;

- iv) The selection criteria for HCP(s) to attend the conference or meeting is based on their interest in the scientific area being discussed at the conference/meeting and their ability to communicate any relevant information to New Zealand HCPs to enhance the quality use of prescription medicines;
- v) The conference/meeting related expenses that will be the responsibility of the sponsored HCP, the sponsoring company, and/or the responsibility of other sources of funding must be clearly communicated in advance. The sponsoring company should also reasonably determine if the HCP is being sponsored by another company to allow for coordinated support between the companies;
- vi) Financial support is not offered to compensate the HCP for his/her time spent attending the conference or meeting;
- vii) It is preferable that payments are made directly to the conference provider;
- viii) In exceptional circumstances, and upon provision of a bona fide receipt, reimbursement may be made to a HCP, e.g. sponsorship of a fixed amount as part payment towards the total cost.

4.16.2 A reasonable level of accommodation expenses may be covered for the conference or meeting attendee. Expenses for family or travelling companion(s) must not be paid by the sponsoring company. The company is expected to make known to the recipient their obligation under the Code and that s/he may not incur additional costs to the company for family members, partners or guests.

4.16.3 Financial assistance for scholarships or other educational funds may be provided to academic or training institutions in order to permit medical students, residents, fellows, and other HCPs in training to attend educational conferences so long as the selection of individuals who receive the funds is made by the academic or training institution.

4.17 Discredit to and Reduced Confidence in the Industry

4.17.1 Company activities with HCPs or materials provided to HCPs must not bring discredit to or reduce confidence in the pharmaceutical industry. A breach of this requirement is a severe breach of this Code of Practice.

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

- The provision of personal services or a benefit in kind to gain access to HCPs.

- An inducement such as a meal, leisure activity or entertainment that is offered as the principal (or only) reason for the activity.
- Unwarranted leisure activities or the provision of entertainment.

4.18 Samples/Starter Packs

4.18.1 Companies shall only provide samples of approved prescription medicines to HCPs with appropriate prescribing rights. Samples must not be sold or traded.

4.18.2 It is not appropriate to provide samples to individual HCPs for their personal use.

4.18.3 Sample/starter packs must only be for approved medicines and must comply with all relevant regulatory requirements.

4.18.4 Companies may provide samples to HCPs who request them. The quantity supplied on any occasion should reflect the reasonable prescribing of the medicine by the HCP. Pressure must not be placed on HCPs to accept samples.

4.18.5 Company representatives are required to hold their Hawker's licence, or be nominated on the company's licence, when carrying and issuing samples/starter packs.

4.18.6 Company representatives are required to record the issuing of any sample/starter pack and gain a signature of receipt from the HCP receiving the sample/starter packs.

4.18.7 Company representatives must take adequate precautions to ensure the security of sample/starter packs in their possession. Companies should develop an appropriate recording system so that if a product recall is necessary, relevant sample/starter packs will be included in the recall.

4.18.8 Sample/starter packs when sent by mail or courier must be packaged so as to be reasonably secure against the package being opened by young children. When sample/starter packs are despatched, they must be traceable. There must be nothing on the packaging that indicates the nature of the contents.

4.18.9 Distribution of sample/starter packs in hospitals must comply with individual hospital requirements.

4.18.10 On request, companies must promptly accept the return of company sample/starter packs.

5. Interactions and Relationships with the General Public, Patients and Patient Organisations

5.1 General

5.1.1. Pharmaceutical companies can interact with patients or patient organisations to provide awareness and information to the public, patients, or carers, with the objective of enhancing the quality use of medicines and improving health outcomes for New Zealanders. Promotion to patient organisations and patients must comply with the requirements of DTCA obligations and this Code.

5.1.2 Enquiries regarding the use of products must be handled by appropriately trained personnel. Requests to companies from individual members of the public for personal advice on the diagnosis of disease or choice of therapy must always be politely refused and such individuals should be advised to consult their HCP.

5.1.3 Material for distribution to the public must be presented in such a way as to avoid the risk of raising unfounded hopes in the public mind as to the results of treatment with a product. Information in such material should be accurate, fair, balanced, not misleading, adhere to the highest standards of accuracy and support the role of the HCP.

5.1.4 All material intended for use by, or distributed to, members of the general public must comply with the relevant sections of this Code, including DTCA obligations (see section 5.11) or Patient Education (see section 5.12). This includes educational items given to HCPs that are intended for distribution to patients.

5.1.5 Companies must not engage in product promotion when supporting patient organisations through the provision of logistical support for patient organisation activities, providing grants and sponsorships to patient organisations, attending patient organisation fundraising activities and in any partnership arrangements between companies and patient organisations.

5.1.6 Appropriately trained personnel can provide medical education, which should be non-promotional, accurate, fair, balanced, not misleading, adhere to the highest standards of accuracy and support the role of the HCP.

5.2 Grants to Patient Organisations

All company interactions with patient organisations must:

- a) respect the independence of the patient organisation and its members;
- b) not place at risk public trust in the pharmaceutical industry;
- c) be conducted fairly; and
- d) be open and transparent.

5.3 Types of Financial or Non-Financial Support

Companies may provide financial or non-financial support for bona-fide/legitimate patient organisation programmes, for example:

- a) patient market research surveys;
- b) event support (the same principles that apply for external meeting sponsorship and/or support in section 4.9 apply to event support);
- c) patient education programme and materials;
- d) care giver education;
- e) attendance at an educational meeting or conference (but, refer to 5.7 for sponsorship of patients);
- f) organisational infrastructure support, e.g. build or upgrade a website; and
- g) disease awareness campaigns.

5.4 Single Company Funding

Companies may not request to be the sole funder of a patient organisation or any of its programmes. This would not preclude a company from being the sole funder of a patient organisation or programme as long as the company does not request this, either directly or indirectly. A company must not ask a patient organisation to provide information on its partnerships with other pharmaceutical companies.

5.5 Methods of Funding

All financial payments or other contributions to a patient organisation must be made directly to the organisation and not to any individual in the patient organisation. Such payments or contributions, or any other form of material support to a patient organisation, must be

formalised in a written agreement or exchange of letters between the company and patient organisation and describe clearly the nature of the support.

5.6 Use of Patient Organisation Logo

A company must not make use of a patient organisation logo or proprietary material without the organisation's written agreement. In seeking permission, the company must clearly state the way in which the logo or material will be used.

5.7 Sponsorship of Patients

Where a company agrees to sponsor any patient(s) to attend third-party educational events, sponsorship payments must be made to the patient organisation and not the patient(s). Companies must not have any involvement in decisions about which patients are to benefit from the sponsorship, such decisions being at the sole discretion of the patient organisation. Such sponsorship must be documented in a written agreement or exchange of letters and must:

- a) be able to successfully withstand public and professional scrutiny;
- b) conform to community standards of ethics and good taste; and
- c) have as its purpose the quality use of medicines in New Zealand.

5.8 Editorial Control

A company may not seek to influence the content of any communication material produced by a patient organisation, except where that content relates to the company's logo or proprietary material. Companies may ask to correct any factual inaccuracies in such material.

5.9 Engaging Patients to Perform Professional Services

5.9.1 Individual patients may be engaged by companies for the purposes of providing insight on living with a disease, the challenges facing patients and their families, and the role that medicines play in the management of their disease; and for providing insight on how to support HCPs who in turn support patients. Examples of such activities include speaking, acting as consultants, trainers, or advising on market research, or patient insight programmes.

5.9.2 No individual patient may be retained to perform a professional service in exchange for an explicit or implicit agreement that a member company's products will be used, purchased,

ordered, recommended, or that the member company will receive any other preferential treatment.

5.9.3 Patients must be chosen to perform services based on their qualifications/expertise and their ability to effectively render the services.

5.9.4 The company must have a legitimate business need for information, services or advice which must be documented in advance within the agreement.

5.9.5 Compensation/honoraria for services rendered must be reasonable and never in excess of fair market value. Compensation based on an hourly or daily rate (dependent on the nature of the service) must be agreed in writing in advance. An estimate of time required for the completion of services must be included in the agreement. Compensation may also include reimbursement of required meals, travel, lodging and incidental expenses of the patient in connection with the service. Reimbursement of expenses of any guest of a patient in connection with a professional service is prohibited.

5.9.6 The number of patients retained in service must not exceed the number reasonably required to achieve the company's stated purpose.

5.10 Gifts/Hospitality/Samples to Patients

5.10.1 Gifts and product samples/starter packs must not be provided directly to patients.

5.10.2 Hospitality may only be provided to patients when they are performing a service for a company permitted by this Code, or are attending a permitted medical education meeting or conference and must otherwise comply with the requirements for hospitality to HCPs in section 4.8.2.

5.11 Direct to Consumer Advertising for Prescription Medicines

5.11.1 Information directed to patients must be accurate, balanced, not misleading and due consideration must be given to the role of the HCP and the importance of the prescriber-patient relationship. Controlled drugs cannot be included in DTCA (see section 3.2.11).

5.11.2 DTCA in all media must be pre-vetted and approved by a TAPS adjudicator(s) or TAPS Delegated Authority.

A TAPS DA can approve minor changes to TAPS approved advertisements that:

- follow a TAPS Adjudicator pre-approved campaign and use claims and imagery consistent with that campaign;
- change details relating to Data Sheet updates;
- re-format a pre-approved piece.

5.11.3 DTCA must observe a high standard of social responsibility, and be sensitive to the fact that consumers rely on therapeutic products and services for their health and well-being.

5.11.4 DTCA must not by implication, omission, ambiguity or exaggeration; claim, mislead or deceive or be likely to mislead or deceive consumers or HCPs; abuse the trust of or exploit the lack of knowledge of consumers or HCPs; exploit the superstitious, or without justifiable reason play on fear.

5.11.5 DTCA must not have depictions that unduly glamorise the product or portray unrealistic outcomes.

5.11.6 DTCA must provide balanced information on the benefits and risks of the product. Specifically, risks and safety information in DTCA must be presented in clear, understandable language, without distraction from the content, and in a manner that supports responsible dialogue between patients and HCPs.

5.11.7 BNR items are prohibited from use in DTCA.

5.11.8 Direct product comparisons with the aim of encouraging the consumer to consider a choice between two different medicines may cause consumer confusion and are prohibited in

DTCA. Companies must respect that individual treatment decisions should be based on a prescriber's broad knowledge and understanding of all treatment alternatives and on an open and positive dialogue between prescriber and patient.

5.11.9 Pre-campaign notification must be given to doctors and pharmacists at least seven days before the commencement of any DTCA campaign.

5.11.10 DTCA for prescription medicines, in language and format that is easily understood by members of the public, must include the following information:

- a) The medicine's classification.
- b) The brand and approved name (usually the INN) of the medicine.
- c) The quantities of the active ingredients in the medicine.
- d) The name of the sponsor and the locality of the registered office.
- e) The approved indication of relevance to the advertisement.
- f) A statement that "Brand Name X has risks and benefits".
- g) A statement that additional product information and Consumer Medicine Information (CMI) can be obtained, and how it can be obtained e.g. company website or 0800 free phone number.

5.11.11 DTCA must also include the following, or similar, statements:

- a) "Ask your doctor if (product name) is right for you."
- b) "Use strictly as directed."
- c) "If symptoms continue or you have side effects, see you doctor, pharmacist or healthcare professional".
- d) A clear statement regarding the funding status of the product that can be understood by members of the public. Examples include:
 - X is an unfunded medicine – a pharmacy charge will apply;
 - X is a partially funded medicine – a pharmacy charge will apply.
- e) A statement that normal doctor's charges apply.
- f) The TAPS approval number and/or TAPS DA number as per section 5.11.2 (in relation to minor changes).

A TAPS approval number is required, but does not need be included in television and radio advertisements.

DTCA may be printed with, or accompanied by the product CMI, however the inclusion of the CMI does not in itself satisfy the other requirements outlined in sections 5.11.10 and 5.11.11 above.

Written promotional material should include the most important information on the common and serious adverse events associated with the use of the product being promoted.

5.11.12 Advertisements should allow the reader, viewer or listener to easily obtain and understand the information as outlined in 5.11.10 and 5.11.11.

5.11.13 Advertisements on television and radio must be no less than 30 seconds in duration. Any written words that must be included in an advertisement in order to avoid contravention of the Medicines Act shall be exposed in clearly legible lettering for a length of time sufficient to enable them to be read by the ordinary viewer.

5.11.14 Direct mail marketing programmes to consumers must allow for the consumer to opt out of receiving further mailings. Collection and use of consumer information by companies must comply with all privacy legislation.

5.11.15 Promotional competitions in relation to prescription medicines directed at consumers or the general public are prohibited.

5.12 Patient Education Materials and Activities

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

5.12.2 Disease awareness activities provide information, promote awareness and educate the public about health, disease and their management. The emphasis must be on the condition and its recognition rather than treatment options (e.g. cover key characteristics of the disease). Such activities must not reference a specific medicine. The awareness activity may

make reference to the availability of different treatment options, however, it may not be designed to encourage a patient to request the prescription of a specific medicine.

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

5.12.4 The educational material must be current, accurate and balanced, and must be presented in such a way so as to avoid the risk of raising unfounded hopes of successful treatment.

5.12.5 The educational material must include the name and the locality of the registered office of the provider of the material.

5.12.6 The educational material must include a statement directing the patient to seek further information about the condition or treatment from his/her HCP.

5.12.7 The tone of the material must not unnecessarily cause alarm or misunderstanding in the community.

5.12.8 Patient education materials must not include promotional claims unless they fulfil the requirements for DTCA.

5.12.9 All patient education materials must be pre-vetted and approved by the TAPS adjudicator, or TAPS DA as per clause 5.11.2 (in relation to minor changes).

5.13 Patient Support Programmes (PSPs)

5.13.1 Companies may arrange or become involved in programmes that support patients already prescribed a prescription medicine to improve positive health outcomes. In the conduct of such programmes, companies must ensure that any statements made, or material provided to members of the general public, are not promotional and could not be considered as having the intention of promoting a prescription medicine to members of the general public, unless the materials comply with section 5.11.10 and 5.11.11 of this Code.

5.13.2 Companies must ensure compliance with the following requirements if they are considering becoming involved in any patient support programme.

- a) Any payment for work undertaken by HCPs involved in such programmes is commensurate with the work undertaken.
- b) No incentives, other than educational materials or items that will enhance positive health outcomes and adherence, are provided to patients to become involved in these programmes.
- c) The programme complies with New Zealand privacy legislation and ethics committee requirements where appropriate.
- d) Any adverse events disclosed in the conduct of any PSP must be reported in accordance with relevant laws and this Code (see section 2.4).
- e) All information provided to patients must comply with relevant sections of this Code.
- f) The duration of these programmes is appropriate to the disease state treated by the product involved.
- g) Collective and anonymised data from such programmes may be presented to HCPs to convey the impact (e.g. benefits or risks) of such programmes on patient outcomes.

5.14 Consumer Trade Displays

5.14.1 Consumer trade displays, and all promotional material used at a consumer trade display, must comply with the requirements for DTCA as outlined in this Code.

5.14.2 A consumer trade display must include the name of the sponsoring company.

5.14.3 Companies must ensure that any overseas affiliates sponsoring or involved in consumer health fairs, or similar, are made aware of and comply with this Code.

5.14.4 Competitions associated with consumer trade displays are prohibited.

5.14.5 Gifts, cash payments and/or donations to charities or societies must not be offered to consumers as an incentive to visit consumer trade display stands.

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

5.14.7 The products/indications being promoted must have approval in New Zealand.

6. Media Relations

6.1 Media Releases

6.1.1 Companies may provide information about a product to the lay press and news media only after the product (or indication) has been approved in New Zealand. This may be considered promotion and, if so, must comply with the relevant sections of this Code, e.g. media releases to the general public are likely to be considered DTCA.

6.1.2 With appropriate consent, companies should provide a list of specialist medical societies and independent medical specialists/experts from whom the editor or journalist can get more information. This helps to provide fair balance for the editor or journalist. In media activities about safety issues, Medsafe should also be listed.

6.1.3 Testimonials, such as patient stories, are prohibited in DTCA, and therefore also in company media releases. This does not preclude a patient(s) from being listed as a contact (following consent), and the media contacting the patient(s) independently.

6.1.4 HCP endorsement of a product in media releases to the public is prohibited. Care should be taken to ensure quotes from HCPs in company media activities do not imply HCP endorsement.

6.1.5 An announcement of the introduction of a new medicine to consumers must not be made by press conference or formal press release until the appropriate steps have been taken to inform the relevant HCPs of its availability.

6.1.6 Companies responding to media enquiries must ensure that the content of the response is confined to what is reasonably necessary to respond to the original enquiry; content that goes beyond what is reasonably necessary may be deemed advertising and therefore subject to the requirements of this Code for DTCA.

6.1.7 Conduct by agencies engaged by a company in relation to media activities and product launches will always be treated as conduct authorised by the company, unless the company can demonstrate that the agency has acted contrary to the company's express instructions or that the agency has otherwise acted in bad faith.

6.1.8 Company initiated media releases intended for HCPs need to conform with the requirements of section 3.10.7.

7. Programmes for Access to Unregistered and/or Unfunded Medicines

7.1 General Provisions

7.1.1 All clinical trials must be conducted in accordance with New Zealand Guidelines for Good Clinical Research Practice. The following provisions apply to research carried out by a company or by an organisation acting under the company's direction. All research activities must comply with New Zealand's privacy laws. Research must only be conducted by suitably qualified and experienced individuals or organisations.

7.1.2 Clinical studies must be designed to answer a valid scientific question and must have appropriate ethics committee approval.

7.1.3 The parameters for access to unregistered and/or unfunded medicines must be transparent for clinicians and patients.

7.2 Clinical Trial Guidelines

7.2.1 All clinical trials conducted in New Zealand must be conducted in accordance with the *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)*. This applies whether or not approval under the Medicines Act is required for the trial. Where CPMP/ICH/135/95 does not cover, or is in conflict with particular provisions of the Medicines Act 1981 or other relevant New Zealand legislation, the *Guideline on the Regulation of Therapeutic products in New Zealand Part II, Section 5: Good Clinical Practice Requirements* must be followed.

7.3 Compassionate Use

7.3.1 Compassionate use access is intended to facilitate the availability to patients of new treatment options under development, and may include provision of medicines under clinical trial conditions or those products or indications that are unregistered. The parameters for compassionate use should be transparent and clearly communicated to patients. Consent should be obtained to confirm the patient has been advised of the parameters.

7.4 Product Familiarisation Programmes

7.4.1 Companies must ensure that all product familiarisation programmes (PFPs) have the aim of allowing the medical profession to evaluate and become familiar with a product.

7.4.2 PFPs may be initiated at any time following registration of the product; or the registration of a new indication.

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

7.4.4 PFPs must only be used and promoted for approved indications of the product.

7.4.5 The enrolment period for PFPs should not exceed 6 months. However, companies may extend this period where there is a strong clinical and/or equity rationale for such an extension.

7.4.6 The length of time each patient may receive treatment under a PFP should be determined by the clinical rationale. This timing should be clearly communicated to HCPs who in turn advise patients prior to commencing the PFP.

7.4.7 Written patient information must be prepared by a company and given to HCPs participating in the PFP. This information must explain that the product will be provided under a PFP for a fixed period, after which it may only be available on a private prescription if the product is not reimbursed by PHARMAC. Consent should be obtained to confirm the patient has been advised of these conditions of enrolment.

7.4.8 PFPs do not preclude the ongoing supply of a medicine within a compassionate use programme.

7.4.9 No formal protocol is required for PFPs.

7.4.10 The collection and publishing of individual patient data from PFPs are not permitted. However, aggregated data on a HCP's experience with the product may be collected and published.

8. Market Research

8.1 All market research must comply with the Constitution and Code of Practice of the Market Research Society of New Zealand or an appropriate alternative of an equivalent standard market research association constitution and code of practice. If engaging the services of a third party to conduct market research, companies must ensure that the contract of service states that, the third party will abide by the relevant constitution and code of practice.

8.2 The sole purpose of market research must be to collect data. Market research activities must not be used as a means to promote to and/or reward HCPs. Market research should not be able to be confused with promotion or a competition, and should be a genuine initiative to collect relevant and useful information to enhance the quality use of prescription medicines.

8.3 The conduct of market research, whether it is carried out directly by the company or by a third party acting under its direction, must not bring discredit upon, or reduce confidence in, the pharmaceutical industry.

8.4 Companies must ensure that the requirements of New Zealand's privacy legislation are complied with during market research activities.

8.5 Market research activities must only be undertaken by suitably qualified and experienced individuals or organisations.

8.6 Market research must be clearly identified as such whenever the researchers interact with HCPs or the public.

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

8.8 Any adverse events disclosed in the conduct of any market research must be reported in accordance with relevant laws and this Code (see section 2.4).

9. Corporate Responsibility

9.1 Training

9.1.1 All company employees engaged in promotional activity must be adequately trained and possess sufficient knowledge to carry out their duties in a responsible, ethical and professional manner in accordance with this Code.

9.1.2 All company employees engaged in promotional activity should be adequately trained and possess sufficient medical and technical knowledge to present information on the company's products in a current, accurate, balanced and responsible manner.

9.1.3 Relevant company employees must receive ongoing training in the requirements of this Code.

9.2 Behaviour

9.2.1 The behaviour of company employees must be able to withstand public and professional scrutiny and conform to professional and community standards of ethics and good taste.

9.2.2 The behaviour of company employees must be beyond reproach and must not bring discredit upon the industry. It is expected that all relationships with HCPs are conducted in a professional manner.

9.3 Appointments

9.3.1 Company employees should ensure that the frequency, timing and duration of appointments with HCPs, together with the manner in which they are made, are such so as not to cause inconvenience to the HCP. The wishes of an individual HCP, or the arrangements in force at any particular establishment, must be observed.

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

9.3.3 Under no circumstances shall company representatives pay a fee in order to gain access to a HCP.

9.4 Telephone Promotion

9.4.1 Company representatives must not use the telephone to promote products to HCPs except with the consent of the HCP. Where information about a prescription product is provided to the HCP via the telephone it must be undertaken in an appropriate and responsible manner so as not to cause any inconvenience or concern to the HCP.

9.5 Product Data Sheets

9.5.1 Company representatives, when engaging in promotional activity, must be able to provide the relevant Data Sheet to an individual HCP, or explain how the Data Sheet can be obtained.

9.5.2 On completing a promotional demonstration, company representatives must offer the relevant Data Sheet to the individual HCP or audience, or explain how the Data Sheet can be obtained.

9.6 Off-label Promotion

9.6.1 Unregistered products or indications must not be promoted. Following an unsolicited request from a HCP (including reprints of journal articles) about an unregistered product or indication, the request must be directed to the company medical department for a response.

9.6.2 Company medical staff responsible for the co-ordination of clinical trials being conducted in NZ may provide appropriate information, including information about unregistered products or indications, to investigators as part of the conduct of trials.

10. Administration of the Code

The administration of this Code is supervised by the Association's secretariat (Secretariat) and the Code of Practice Standing Committee (COPSC).

The COPSC shall receive and determine any complaint by any person that a member company is, or has been, in breach of the Code. The COPSC is responsible to the Association's Board of Directors (Board).

10.1 The Code of Practice Standing Committee

10.1.1 Membership. The COPSC is comprised of six members as follows:

- (a) A practising or retired judge, solicitor or barrister as chairperson (Chairperson)
- (b) One medical practitioner currently registered with the Medical Council of New Zealand, nominated by the NZMA
- (c) One pharmacist with clinical experience or a clinical pharmacologist
- (d) Two member company representatives. These include:
 - (i) one senior medical department representative - on a rotational basis, and
 - (ii) one company managing director, also on a rotational basis.
- (e) One non-voting Association representative; a staff member with delegated responsibility for handling of COP complaints and attendance at meetings.

10.1.2 In exceptional circumstances, in order to meet timelines, in agreement with the Chairperson, complainant, and respondent, the composition of the committee may be modified.

10.1.3 When a complaint has been lodged, the non-voting Association representative shall schedule a meeting of the COPSC to be held within six weeks. All reasonable efforts will be made to schedule a meeting earlier if the Chairperson considers the complaint to be urgent.

10.1.4 In cases where the complainant alleges what appears to be a very serious and obvious breach of the Code an emergency meeting may be called.

10.1.5 Prior to accepting an invitation to sit as a member of the COPSC, individuals are required to declare any potential or existing conflict of interests. Where a potential or existing conflict of interest exists, a decision about whether that person can sit on the COPSC will be made by the Chairperson and General Manager of Medicines New Zealand (General Manager), and agreed by the complainant and respondent. No person with a potential or existing conflict of interest can act as Chairperson. Decisions relating to conflicts of interest agreed in this manner cannot be appealed. Where possible the COPSC will avoid appointing members with potential or existing conflicts of interest.

10.2 The Complaints Process

10.2.1 Complaints must be made in writing and addressed to the General Manager.

10.2.2 Acceptance of a complaint is at the discretion of the Association. For example, a complaint may not be accepted if the complaint has already been dealt with by the COPSC or matters relevant to the complaint are subject to legal or other administrative proceedings.

10.2.3 Any member of the Association who lodges a complaint is required to include an administration fee of \$6,500 (plus GST). The administration fee will be forfeited if the complainant is unsuccessful and refunded if successful. Where the COPSC makes a decision against the respondent the administration fee will be charged to the respondent.

10.2.4 Any non-member of the Association who lodges a complaint is required to include an administration fee of \$7,500 (plus GST). The administration fee will be forfeited if the complainant is unsuccessful and refunded if successful. Where the COPSC makes a decision against the respondent an administration fee of \$6,500 (plus GST) will be charged to the respondent.

10.2.5 All complainants are encouraged to try and resolve their complaints directly with the relevant company in the first instance. Any communications made during such an attempt may be taken into account by the COPSC when making its decision.

10.2.6 Any member of the public, or patient organisation, who lodges a complaint may apply to the General Manager for a fee waiver which may be granted at the full discretion of Medicines New Zealand.

10.2.6.1 The General Manager will determine if the complaint is reasonable, and if the administration fee should be waived.

10.2.6.2 If the complaint is considered reasonable, and the fee is to be waived, the complainant will be notified and the complaint sent to the COPSC. If the complaint is upheld by the COPSC the respondent company will be charged an administration fee of \$6,500 (plus GST). If the complaint is unsuccessful no administration fee will be charged to any party.

10.2.6.3 If the complaint is considered unreasonable or that the administration fee should be charged to the complainant, the complainant will be so advised. The complainant may refer an adverse decision by the General Manager to the Board. If the Board considers the complaint is unreasonable or that an administration fee should be paid, the complainant will be so advised. The Board's decision on whether the complaint should be referred to the COPSC or an administration fee charged shall be final.

10.2.6.4 In cases where the complaint is considered reasonable, but that an administration fee should be charged to the complainant, the complaint will be heard by the COPSC only if the complainant pays an administration fee of \$7,500 (+GST), which will be refunded if the complaint is subsequently upheld and forfeited if unsuccessful. Where the COPSC makes a decision against the respondent an administration fee of \$7,500 (plus GST) will be charged to the respondent.

10.2.6.5 If the complainant is a member of the public, they may apply to the General Manager to have their name withheld from the respondent and from public release.

10.2.7 All complainants should clearly state the nature of the complaint and the sections of the Code alleged to have been breached. The complaint must be accompanied by all previous correspondence relating to it.

10.2.8 All complaints are to be lodged by email and hardcopies by courier or post (8 copies) with the Association for distribution to the COPSC and to the respondent.

10.2.9 The Secretariat will send copies of the complaint to the respondent by email or courier; this will serve as notice of the complaint to the respondent.

10.2.10 The respondent may respond in writing to the complaint and any such response must be received by the COPSC within nine working days of the respondent receiving the complaint. Eight copies of the response are to be lodged with the Association for distribution to the COPSC and to the complainant.

10.2.11 If no response is received from the respondent within the period of nine working days, the COPSC may consider and determine the complaint in the absence of any response from the respondent.

10.2.12 A copy of the respondent's response is to be forwarded to the complainant, no less than six working days prior to the date set for the COPSC's consideration of the complaint. The complainant may make written submissions in reply to the respondent's response.

10.2.13 The COPSC will accept oral submissions. In such cases both parties will be afforded the opportunity to appear before the Committee.

10.2.14 The COPSC will report their determination to the complainant and respondent within five working days of its meeting.

10.2.15 In the absence of an appeal, the COPSC will forward a copy of the determination to all members of the Association once the period to lodge an appeal has lapsed.

10.2.16 The COPSC may alter any of the time frames above in respect of any particular complaint if there are special circumstances and, where appropriate, on written application by either the complainant or respondent.

10.2.17 Members of the COPSC must ensure that meetings and details of the COPSC process are kept confidential, unless otherwise required by law.

10.2.18 Members of the COPSC must not comment to members of the Association or publically on decisions made by the COPSC.

10.3 Sanctions

10.3.1 In making its determination on a complaint, the COPSC may:

- Order a company to suspend or to discontinue an advertisement or a practice and/or
- Require a company to publish a corrective letter; and/or
- Order a company to pay a fine of up to NZ\$ 80,000 (plus GST, if any), the amount of such fine to take into account the seriousness of the breach and the cost of the corrective action ordered; and/or
- Require a company to provide any new promotional material to Medicines New Zealand for scrutiny prior to using such material, for up to six months; and/or.
- Recommend expulsion of a member company to the Medicines New Zealand Board.

10.3.2 Any order made by the COPSC shall take effect five working days after the notification of the COPSC's determination, with the exception of an order that a company suspend or discontinue an advertisement or a practice, which order shall take effect immediately upon notification of the COPSC determination.

10.3.3 Corrective letters, required by the COPSC from a company found to be in breach of the Code, are to be reviewed by the COPSC.

10.3.4 In the event of the COPSC requiring a company to cease or withdraw a promotional activity, the company shall at once comply with the COPSC's ruling pending any appeal against the decision of the COPSC pursuant to the Rules of the Association. A promotional activity thus suspended shall not be reactivated before the appeal process has been concluded, nor shall any other promotional activity thus suspended be recommenced during the period in question.

10.3.5 In the event that a fine is imposed on a member company the value of the fine will be donated to a health related charitable organisation to be determined at the time by the Board of Medicines New Zealand.

10.4 Appeals

10.4.1 An appeal may be lodged by either party with the General Manager within five working days of notification of the COPSC's determination. The appeal will be circulated to both parties and to the Appeal Committee.

10.4.2 An appeal may be lodged where it is alleged that:

- a) the COPSC is wrong in fact; and/or
- b) the COPSC is wrong in interpretation of the Code or procedure.

10.4.3 Any member of the Association who lodges an appeal with the Association (the Applicant) is required to include an administration fee of \$15,000 (plus GST). This fee will be forfeited if the appeal is unsuccessful and refunded if successful. Where the Appeal Committee makes a decision against the respondent the administration fee will be charged to the respondent.

10.4.4 Any non-member of the Association who lodges an appeal with the Association is required to include an administration fee of \$15,000 (plus GST). If the appeal is upheld, the Applicant will be refunded 50% of the administration fee and the respondent will be charged the full administration fee.

10.4.5 Any member of the public or patient organisation who lodges an appeal can request an appeal fee waiver, from the General Manager and/or Board by following the procedure set out for an application fee waiver.

10.4.6 Appeals shall be heard by the Appeal Committee, which is to be convened for each Appeal. The Appeal Committee is comprised of a practising or retired judge, solicitor or barrister as chairperson (Appeal Chairperson), and such other persons as is appropriate according to the complexity of the appeal.

10.4.7 The Appeal Chairperson has authority to co-opt such other persons to the Appeal Committee as may be required for each appeal.

10.4.8 The chairperson of the Appeal Committee shall not be the same person as the chairperson of the COPSC, and shall be appointed by the Association's Board.

10.4.9 The Appeal Committee will determine the procedure to be followed on appeal and may receive submissions from the parties, either orally or in writing.

10.4.10 The Appeal Committee may confirm, modify, or reverse the determination of the COPSC, or make any of the orders set out in 10.3 as may be required.

10.4.11 Decisions of the Appeal Committee will be made available to both parties within 20 working days from the date of the Appeal Committee meeting. The Association will then forward a copy of the Appeal Committee ruling to companies of the Association within five working days from the release of the findings to the parties concerned.

10.4.12 The decision of the Appeal Committee shall be final and take effect immediately upon delivery of the decision.

10.5 Publication of Decisions of the COPSC and Appeal Committee

A summary of the determination of challenges heard by the COPSC and the Appeal Committee will be published on the Medicines New Zealand website.

10.6 Persistent Breaches of the Code

Expulsion from the Association shall be considered by the Board in all cases of persistent and serious breaches of the Code.

10.7 Complaints against Company Non-members

10.7.1 Complaints concerning promotional activities of company non-members will be forwarded to the company non-member with an invitation to have the complaint adjudicated by the COPSC and to abide by the Committee's decision and any sanctions imposed. If the company non-member accepts the invitation to have the complaint adjudicated by the COPSC, the complaint will proceed in accordance with the provisions of this Code.

10.7.2 If the company non-member declines the invitation to have the complaint adjudicated by the COPSC, the Association may forward the complaint to any other relevant body considered to have jurisdiction in the matter.

10.8 Discretion for Referral

The Association may refer any complaint not covered by this Code, or any complaint that may constitute a breach of the law or another code of practice, to any other relevant body considered to have jurisdiction in the matter.

10.9 Abuse of the Code

10.9.1 If in the view of the COPSC a complaint is considered frivolous or vexatious, the COPSC may request the complainant member company to show cause why the Committee should not impose a fine of a maximum of \$75,000 (plus GST, if any), for abuse of the Code.

10.9.2 A member company may be found to breach this section if a single complaint is considered to be frivolous or vexatious or following a series of complaints against a single or number of competitors within a therapeutic class by a single complainant. 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.

10.10 Monitoring

10.10.1 To support compliance with the Code, the Board or its delegate may monitor promotional material and activities of New Zealand pharmaceutical companies on an ongoing basis.

10.10.2 The Board may review all forms of promotional material and all types of promotional activities.

10.10.3 If the Board reaches consensus that any such promotional material or activity appears to be in breach of the Code, the responsible company will be advised and provided the opportunity to respond. The Board, having considered the responsible companies response, may refer the matter to the COPSC, or other appropriate authority, for adjudication as a complaint.

GLOSSARY

Adverse effect/adverse drug reaction/side effect refers to an event contemporaneously associated with the use of a prescription medicine where it is recognised that the probability of causality exists.

Adverse event means any event contemporaneously related to the use of a prescription medicine whether or not the prescription medicine is judged to have caused the event.

Advertisement – As defined in Section 56 of the Medicines Act 1981, “advertisement means any words, whether written, printed, or spoken, and any pictorial representation or design, used or appearing to be used to promote the sale of medicines or medical devices or the use of any method of treatment; and includes any trade circular, any label, and any advertisement in a trade journal; and advertising and advertised have corresponding meanings.” Material that is clearly technical or other data for registration purposes, for in-house company use, or for use by a clinical trial investigator shall not be considered an advertisement for the purposes of this Code.

Association means Medicines New Zealand Incorporated.

Balanced means reasonable representation of both the benefits and risks of a product.

Banner Advertisement means a pull-up stand or flag-style advertisement principally intended to highlight the brand name of a product to HCP meeting attendees.

Brand name reminder BNR item means such items of low monetary value, which are intended to remind HCPs of the existence of a product.

CARM refers to the Centre for Adverse Reaction Monitoring of the NZPhvC.

Celebrity means any person who is well known to the New Zealand public and who may convey enhanced value to their words or actions by virtue of their recognition or status within the public's eye.

Chief Executive means the manager of the local New Zealand pharmaceutical operation (may also be known as the Country Head, Managing Director, General Manager, etc).

CMI refers to Consumer Medicine Information.

Code means the most recent version of the Code of Practice of the Association.

Company means a company or other legal entity supplying prescription medicines in New Zealand.

Company representative means a person expressly employed by or contracted to a company whose main purpose is the promoting of the company's products to HCPs.

Comparison – Company advertising commonly contains comparisons with other products and such comparisons are usually made to show an advantage of the advertised product over its competitor(s).

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 individual health practitioner engaged by a company for expert or professional advice.

Consumer Medicine Information (CMI) - The CMI is regarded as the consumer equivalent to a Data Sheet and should be written at a level that can be readily understood by members of the lay public. The CMI is intended to support safe and effective use of medicines by consumers. Although the preparation of CMI is not mandatory, Medsafe encourages the pharmaceutical industry to prepare CMI for all approved medicines and, in particular, for Prescription Medicines, Restricted Medicines and Controlled Drugs which require prescription, as medicines in these categories present the highest risk if taken inappropriately. However, if a company intends to conduct Direct to Consumer Advertising (DTCA), CMI is required by this Code.

COPSC refers to Code of Practice Standing Committee of Medicines New Zealand.

Correct means representative of all the evaluable data.

Data on File refers to that body of unpublished clinical or scientific information held in company internal reports.

Data Sheet refers to the full product information in the required format, as submitted to and approved by Medsafe of the New Zealand Ministry of Health.

Delegated Authority means an employee of a pharmaceutical company registered with the Therapeutic Advertising Pre-vetting System (TAPS) and authorised by TAPS to review and approve promotional material.

Direct to Consumer Advertising (DTCA) means any advertising or promotional material intended for viewing or distribution to members of the general public (i.e., non-HCPs).

DTCA refers to Direct-to-Consumer Advertising.

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

Entertainment means the provisions of any diversion or amusement.

Full Advertisement means any advertisement that makes a promotional claim.

General availability means available to supply post-gazettal.

General public means persons other than HCPs.

Gift means an item given voluntarily and without compensation.

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

Healthcare Professional (HCP) includes members of the medical, dental, pharmacy or nursing professions and any other persons who in the course of their professional activities may prescribe, supply, recommend or administer a medicine.

Hospitality generally means the provision of food and/or beverages, but may also include the provision of travel expense support. Hospitality does not mean entertainment.

IFPMA refers to International Federation of Pharmaceutical Manufacturers Associations.

Industry means companies supplying prescription medicines in New Zealand.

INN - the International Non-proprietary Name - refers to the non-proprietary, or generic, name given to a pharmaceutical substance.

In-institutional Event An in-institutional event includes for example, journal clubs, grand rounds, multi-disciplinary team meetings, or in service meeting, held within the HCP workplace.

Internet “pop-up” advertisements are advertisements that appear, unsolicited, when the viewer is accessing a website.

Information means educational facts regarding the attributes of a product.

Items of medical utility means the contribution of medical equipment or any item that may improve the quality of health service that can be provided to patients. Items might include an anatomical model for use in an examination room, or medical textbooks, as both primarily involve a patient benefit. A DVD or CD player however would not be permissible. Items should not be offered on more than an occasional basis, even if each individual item is appropriate.

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.

MAAC refers to the Medicines Assessment Advisory Committee to the Therapeutics Section, Ministry of Health of New Zealand.

Mailings means promotional material designed for distribution through the postal system or by private means.

Manufacturer includes the manufacturer, importer or New Zealand distributor of a prescription medicine.

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 claim includes any statement that conveys information about a disease state or the attributes of a product in respect of its therapeutic use, that is, a use for the purpose of or in connection with:

- (a) Preventing, diagnosing, curing or alleviating a disease, defect or injury in man;
- (b) Influencing, inhibiting or modifying a physiological process in man;
- (c) Testing the susceptibility of man to a disease or ailment; or
- (d) Destroying or inhibiting micro-organisms that may be harmful to man.

Medical content means that portion of promotional material that makes a medical claim.

Medicine in this context refers to prescription medicines and vaccines.

Member company means any person, firm or company holding membership to Medicines New Zealand.

MoH refers to the New Zealand Ministry of Health.

New chemical entity means a product containing an active pharmaceutical ingredient which has not been previously included in a product approved in New Zealand for human use, including new combinations, salts or esters of previously marketed substances.

New Indication(s) means an additional indication for a medicine that was approved by Medsafe after the original registration of the medicine.

New Zealand Privacy Legislation means the Privacy Act 1993 and related legislation.

NZMA refers to the New Zealand Medical Association.

NZPhvC refers to the New Zealand Pharmacovigilance Centre.

Patient Advocacy Group refers to organisations, generally non-profit, that represent people with specific diseases or promote aspects of health care.

Patient Support Programme means a programme run by a company with or without involvement from a patient support group, with the aim of increasing patient compliance and positive patient health outcomes.

PPF refers to Product Familiarisation Programme.

PMS refers to Post-Marketing Surveillance.

Post-Marketing Surveillance studies means research intended to generate data on safety parameters of a product that has been approved for registration when used in accordance with the approved Product Information.

Product means any pharmaceutical dose form and/or delivery method that is approved by the Ministry of Health, Medsafe for human therapeutic use, provided that such compound has been scheduled for sale or distribution by prescription only or that such compound is primarily promoted to HCPs for the purpose of encouraging them to prescribe or recommend usage of that compound.

Product Familiarisation Programme means a programme run by a company with the aim of allowing the medical profession to evaluate and become familiar with the product.

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

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

Promotional material means any and all representation concerning the attributes of a product conveyed by any medium (including electronically) and in many media (including websites) whatever for the purpose of encouraging the use of that product.

Reference manual is a serial or monographic publication designed by its publisher to provide information in classified sequence for the purposes of ready reference to pharmacological or medical data.

RNZCGP refers to the Royal New Zealand College of General Practitioners.

Sample(s) - See Starter Pack.

Satellite meetings are meetings held in conjunction with international or Australasian congresses and are under the auspices of the Society, College or other non-company entity in question.

SCOTT refers to the Health Research Council's Standing Committee on Therapeutic Trials.

Short advertisement is the type of advertisement that is designed to remind a prescriber of a product's existence but must not contain promotional claims.

Social media (such as Facebook, YouTube, Myspace, blogs, Twitter and wikis), is an umbrella term that defines the various activities that integrate technology, social interaction, and the creation of content. Software tools can allow groups to generate content and engage in peer-to-peer conversations and exchange of content.

Sponsorship means the provision of financial support to a person or for an event carried out by another.

Sponsorship advertisement means an advertisement that represents that the advertiser is sponsoring a person, competition, activity or event.

Starter pack means a quantity of a product supplied without cost to HCPs. Starter packs are also referred to as “samples” by HCPs.

Substantiation means to give reasonable grounds in support of a promotional claim. Substantiating information should conform to the requirements of the Code and must not rely solely on data on file.

Symposium means a scientific meeting sponsored by a company as an independent event or as a satellite to a congress.

TAPS means the Therapeutic Advertising Pre-Vetting Service. The role of TAPS is to ensure that advertisements are compliant with the NZ medicines legislation and the Advertising Standards Authority Codes. **TAPS Adjudicator** means an individual commissioned by the Association of New Zealand Advertisers (ANZA) to review and approve promotional material and to provide support to company Delegated Authorities on matters related to advertising and promotion of medicines. The TAPS Adjudicators are not able to approve marketing activities that are planned in conjunction with the advertising. It is the responsibility of the company to ensure the marketing activities undertaken are compliant with the Medicines New Zealand Code.

Testimonial is an uncontrolled anecdotal report of the beneficial effect of a product or treatment of one individual

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

Therapeutic products mean therapeutic goods or services or any goods and services which claim a therapeutic purpose as defined by Section 4 of the Medicines Act 1981.

Therapeutic purpose/claim is quite comprehensive in the Medicines Act and covers some key aspects regarding therapeutic products and use.

- a) Treating or preventing disease
- b) Diagnosing disease or ascertaining the existence, degree or extent of a physiological condition
- c) Effecting contraception
- d) Inducing anaesthesia
- e) Altering the shape, structure, size or weight of the human body

- f) Otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way;
or
- g) Cleaning, soaking or lubricating contact lenses.

Trade display *see Professional Trade Display.*

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

Unique means being the first, different from all others and the only one of its class on the New Zealand market.

Unsolicited means given or sent without being asked for.

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