



CODE OF PRACTICE

for the

PHARMACEUTICAL

INDUSTRY

2006

PRESCRIPTION MEDICINES
CODE OF PRACTICE AUTHORITY



CODE OF PRACTICE
for the
PHARMACEUTICAL INDUSTRY

2006 Edition

together with the

PRESCRIPTION MEDICINES
CODE OF PRACTICE AUTHORITY
Constitution and Procedure

PRESCRIPTION MEDICINES
CODE OF PRACTICE AUTHORITY

This edition of the Code of Practice comes into operation on 1 January 2006. During the period 1 January 2006 to 30 April 2006, no promotional material or activity will be regarded as being in breach of the Code if it fails to comply with its provisions only because of requirements which this edition of the Code newly introduces.

THE PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY

The Prescription Medicines Code of Practice Authority was established by The Association of the British Pharmaceutical Industry in 1993 to operate the Code of Practice for the Pharmaceutical Industry independently of the Association itself.

Complaints about the promotion of medicines should be submitted to the Director of the Prescription Medicines Code of Practice Authority, 12 Whitehall, London SW1A 2DY, telephone 020-7930 9677, facsimile 020-7930 4554, email complaints@pmcpa.org.uk.

Complaints made under the Code about promotional material or the promotional activities of companies are considered by the Code of Practice Panel and, where required, by the Code of Practice Appeal Board. Reports on cases are published by the Authority and are available on request and on the Authority's website www.pmcpa.org.uk.

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PHARMACEUTICAL INDUSTRY

2006 Edition

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In the Code of Practice, guidance on the interpretation of the Code appears as supplementary information to the text against a pale blue background.

CODE OF PRACTICE *for the* PHARMACEUTICAL INDUSTRY

INTRODUCTION

Promoting Appropriate Use of Medicines

The pharmaceutical industry in the United Kingdom is committed to benefiting patients by operating in a professional, ethical and transparent manner to ensure the appropriate use of medicines and support the provision of high quality healthcare. This commitment applies to all with whom the industry interacts. To demonstrate this commitment The Association of the British Pharmaceutical Industry (ABPI), which represents the UK industry, decided that certain activities should be covered in detail and thus agreed the ABPI Code of Practice for the Pharmaceutical Industry. The Code covers the promotion of medicines for prescribing to both health professionals and appropriate administrative staff. In addition it sets standards for the provision of information about prescription only medicines to the public and patients, including patient organisations.

In addition to the Code there is extensive UK and European law relating to the promotion of medicines. The Code reflects and extends beyond the relevant UK law.

The aim of the Code is to ensure that the promotion of medicines to health professionals and to administrative staff is carried out within a robust framework to support high quality patient care. As well as covering printed materials, it controls samples, meetings, promotional aids and the provision of medical and educational goods and services. The Code also sets standards relating to the provision of information to patients and the public as well as relationships with patient groups. The industry considers that provided the requirements of the Code are met, working with patients and patient organisations can bring significant public health benefits. These requirements also apply to working with all user groups, such as disability associations, relative and carer associations and consumer associations.

In summary, companies must ensure that their materials are appropriate, factual, fair and capable of substantiation and that all other activities are appropriate and reasonable.

Ensuring High Standards

The detailed provisions in the Code are to ensure that pharmaceutical companies operate in a responsible, ethical and professional manner. Whilst the industry has a legitimate right to promote medicines to health professionals, the Code recognises and seeks to achieve a balance between the needs of patients, health professionals and the public, bearing in mind the political and social environment within which the

industry operates and the statutory controls governing medicines. The availability of accurate up-to-date information is vital to the appropriate use of medicines. Pharmaceutical companies must ensure that enquiries about their medicines are answered appropriately in a timely manner.

Strong support is given to the Code by the industry with all companies devoting considerable resources to ensure that their activities comply with it. Any complaint made against a company under the Code is regarded as a serious matter both by that company and by the industry as a whole. Sanctions are applied against a company ruled in breach of the Code.

Companies must ensure that all relevant personnel are appropriately trained in the requirements of the Code and must have robust operating procedures under which all materials and activities covered by the Code are reviewed to ensure compliance both with the Code and with the appropriate legal requirements.

The Code incorporates the principles set out in:

- the International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA) Code of Pharmaceutical Marketing Practices
- The European Federation of Pharmaceutical Industries and Associations' (EFPIA) Code of Practice on the Promotion of Medicines
- Directive 2001/83/EC on the community code relating to medicinal products for human use, as amended by Directive 2004/27/EC
- The World Health Organisation's Ethical criteria for medicinal drug promotion.

The Code covers the industry's activities only. However those interacting with industry as individuals or organisations also have a responsibility to ensure that their interactions comply with relevant legal requirements and are asked to follow the Code where relevant and not make requests that are not in accordance with the Code. Most of those interacting with the industry, other than patients, are covered by a selection of professional codes and guidance. For example, the General Medical Council guidance 'Duties of a Doctor', the Royal Pharmaceutical Society of Great Britain Code of Ethics and Standards and the Nursing & Midwifery Council Code of Professional Conduct: standards for conduct, performance and ethics. Patient organisations are likely to be covered by Charity Commission rules as well as their own codes. The pharmaceutical industry is encouraged to take into account all relevant codes and guidance as well as the ABPI Code.

Transparency

The industry recognises that transparency is an important means of maintaining confidence. The operation of the Code, including the complaints

procedure, is a demonstration of the industry's commitment to transparency as are the requirement to declare pharmaceutical company involvement in activities and materials and the publication of detailed reports of cases considered under the Code. Although not a requirement of this Code, the industry's global agreement to disclose certain clinical trial data is another example of the industry's commitment to transparency. Further information can be found in the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases 2005.

Sanctions

In each case where a breach of the Code is ruled, the company concerned must give an undertaking that the practice in question has ceased forthwith and that all possible steps have been taken to avoid a similar breach in the future. An undertaking must be accompanied by details of the action taken to implement the ruling. At the conclusion of a case a detailed case report is published.

Additional sanctions are imposed in serious cases. These can include:

- the audit of a company's procedures to comply with the Code, followed by the possibility of a requirement for the pre-vetting of future material
- recovery of material from those to whom it has been given
- the issue of a corrective statement
- a public reprimand
- advertising in the medical and pharmaceutical press of brief details of cases in which companies were ruled in breach of Clause 2 of the Code, were required to issue a corrective statement or were the subject of a public reprimand
- suspension or expulsion from the ABPI.

Monitoring of Activities and Guidance

The Prescription Medicines Code of Practice Authority (PMCPA) arranges for advertising and meetings to be regularly monitored. The PMCPA also provides informal guidance about the Code and its operation.

Promoting Health

The commitment of Britain's pharmaceutical industry to providing high quality effective medicines brings major benefits to both the nation's health and economy.

The National Health Service spends more than £9.4 billion a year on medicines, representing less than 11 per cent of its total expenditure. Medicine exports are worth over £12.3 billion a year – the UK's third largest foreign exchange earner in manufactured goods. Nearly a quarter of the world's top 100 medicines were discovered in Britain.

Investment into researching and developing new products in the UK is now running at around £3.2

billion a year and each new medicine takes an average of ten to twelve years to develop before it is authorized for use, with no guarantee of commercial success.

The Association of the British Pharmaceutical Industry and its Code of Practice

The Association of the British Pharmaceutical Industry (ABPI) is the trade association representing manufacturers of prescription medicines. It was formed in 1930 and now represents about seventy-five companies which supply more than 80% per cent of the medicines used by the National Health Service.

The Code has been regularly revised since its inception in 1958 and is drawn up in consultation with the British Medical Association, the Royal Pharmaceutical Society of Great Britain and the Medicines and Healthcare products Regulatory Agency of the Department of Health. This edition of the Code was drawn up following consultation with many stakeholders, including patient organisations. Any individual who wished to comment was invited to do so via the ABPI website.

It is a condition of membership of the ABPI to abide by the Code in both the spirit and the letter. Companies which are not members of the ABPI may give their formal agreement to abide by the Code and accept the jurisdiction of the Prescription Medicines Code of Practice Authority and about sixty have done so. The current list can be found on the PMCPA website www.pmcpa.org.uk. Thus the Code is accepted by virtually all pharmaceutical companies operating in the UK.

Administering the Code of Practice

The Code is administered by the Prescription Medicines Code of Practice Authority which is responsible for the provision of advice, guidance and training on the Code as well as for the complaints procedure. The PMCPA operates independently of the ABPI itself. The relationship between the PMCPA and the ABPI is set out in a protocol of agreement. Financial information about the PMCPA is published in its Annual Report.

PMCPA publications can all be found on the website or are supplied on request.

Complaints which are made under the Code are considered by the Code of Practice Panel and, where required, by the Code of Practice Appeal Board. Reports on completed cases are published by the PMCPA. The PMCPA publishes a list of ongoing cases on its website.

How to Complain

Complaints should be submitted to the Director of the Prescription Medicines Code of Practice Authority, 12 Whitehall, London SW1A 2DY, telephone 020-7930 9677, facsimile 020-7930 4554, email complaints@pmcpa.org.uk.

PROVISIONS OF THE CODE OF PRACTICE

CODE OF PRACTICE

Clause 1 Scope of the Code and Definition of Certain Terms

1.1 This Code applies to the promotion of medicines to members of the United Kingdom health professions and to appropriate administrative staff.

The Code also applies to a number of areas which are non-promotional, including information made available to the general public about prescription only medicines.

It does not apply to the promotion of over-the-counter medicines to members of the health professions when the object of that promotion is to encourage their purchase by members of the public.

1.2 The term 'promotion' means any activity undertaken by a pharmaceutical company or with its authority which promotes the prescription, supply, sale or administration of its medicines.

It includes:

- journal and direct mail advertising
- the activities of representatives including detail aids and other printed material used by representatives
- the supply of samples
- the provision of inducements to prescribe, supply, administer, recommend, buy or sell medicines by the gift, offer or promise of any benefit or bonus, whether in money or in kind
- the provision of hospitality for promotional purposes
- the sponsorship of promotional meetings
- the sponsorship of scientific meetings including payment of travelling and accommodation expenses in connection therewith
- all other sales promotion in whatever form, such as participation in exhibitions, the use of audio-cassettes, films, records, tapes, video recordings, radio, television, the Internet, electronic media, interactive data systems and the like.

It does not include:

- replies made in response to individual enquiries from members of the health professions or appropriate administrative staff or in response to specific communications from them whether of enquiry or comment, including letters published in professional journals, but only if they relate solely to the subject matter of the letter or enquiry, are accurate and do not mislead and are not promotional in nature
- factual, accurate, informative announcements and reference material concerning licensed medicines and relating, for example, to pack changes, adverse-reaction warnings, trade catalogues and price lists, provided they include no product claims
- information supplied by pharmaceutical companies to national public organizations, such as the

SUPPLEMENTARY INFORMATION

Clause 1.1 Scope of the Code

For the purposes of the application of the Code, the United Kingdom includes the Channel Islands and the Isle of Man.

The Code applies to the promotion of medicines to members of the health professions and to appropriate administrative staff as specified in Clause 1.1. This includes promotion at meetings for UK residents held outside the UK. It also applies to promotion to UK health professionals and administrative staff at international meetings held outside the UK, except that the promotional material distributed at such meetings will need to comply with local requirements.

Some of the requirements of the Code are not necessarily related to promotion. Examples include declaration of sponsorship in Clause 9.10, certain aspects of the provision of medicines and samples in Clause 17 and the provision of information to the public in Clause 20.

The Code does not apply to the promotion of over-the-counter medicines to members of the health professions when the object of that promotion is to encourage their purchase by members of the public as specified in Clause 1.1. Thus, for example, an advertisement to doctors for an over-the-counter medicine does not come within the scope of the Code if its purpose is to encourage doctors to recommend the purchase of the medicine by patients. Where the advertisement is designed to encourage doctors to prescribe the medicine, then it comes within the scope of the Code.

Advertisements for over-the-counter medicines to pharmacists are outside the scope of the Code. Advertisements to pharmacists for other medicines come within the scope of the Code.

Clause 1.1 Journals with an International Distribution

The Code applies to the advertising of medicines in professional journals which are produced in the UK and/or intended for a UK audience.

International journals which are produced in English in the UK are subject to the Code even if only a small proportion of their circulation is to a UK audience. It is helpful in these circumstances to indicate that the information in the advertisement is consistent with the UK marketing authorization.

It should be noted that the Medicines and Healthcare products Regulatory Agency's guidance 'Advertising and Promotion of Medicines in the UK', The Blue Guide, differs from the above by stating 'Advertising material in professional journals intended primarily for circulation in the UK whether or not in the English language must comply with UK legislation and with the UK marketing authorization for the product'.

Where a journal is produced in the UK but intended for distribution solely to overseas countries local requirements and/or the requirements of the International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA) Code of Pharmaceutical Marketing Practices should be borne in mind.

National Institute for Health and Clinical Excellence (NICE), the All Wales Medicines Strategy Group (AWMSG) and the Scottish Medicines Consortium (SMC) is exempt from the Code provided the information is factual, accurate and not misleading

- measures or trade practices relating to prices, margins or discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993
- summaries of product characteristics
- European public assessment reports
- UK public assessment reports
- the labelling on medicines and accompanying package leaflets insofar as they are not promotional for the medicines concerned; the contents of labels and package leaflets are covered by regulations
- information relating to human health or diseases provided there is no reference, either direct or indirect, to specific medicines.

1.3 The term ‘medicine’ means any branded or unbranded medicine intended for use in humans which requires a marketing authorization.

1.4 The term ‘health professional’ includes members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities may prescribe, supply or administer a medicine.

1.5 The term ‘over-the-counter medicine’ means those medicines or particular packs of medicines which are primarily advertised to the general public for use in self medication.

1.6 The term ‘representative’ means a representative calling on members of the health professions and administrative staff in relation to the promotion of medicines.

1.7 Pharmaceutical companies must comply with all applicable codes, laws and regulations to which they are subject.

1.8 Each company must appoint a senior employee to be responsible for ensuring that the company meets the requirements of the Code.

Clause 1.1 Advertising to the Public and Advertising Over-the-Counter Medicines to Health Professionals and the Retail Trade

The promotion of medicines to the public for self medication is covered by the Code of Standards of Advertising Practice for Over-the-Counter Medicines of the Proprietary Association of Great Britain (PAGB). The PAGB also has a Code of Practice for Advertising Over-the-Counter Medicines to Health Professionals and the Retail Trade.

Clause 1.1 Promotion to Administrative Staff

The provisions of the Code apply in their entirety to the promotion of medicines to appropriate administrative staff except where the text indicates otherwise. For example, the prescribing information required under Clause 4 must be included in promotional material provided to administrative staff but it is not permissible to provide samples of medicines to them as this is proscribed by Clause 17.1.

Particular attention is drawn to the provisions of Clause 12.1 and the supplementary information to that clause, which concern the appropriateness of promotional material to those to whom it is addressed.

Clause 1.2 Replies Intended for Use in Response to Individual Enquiries

The exemption for replies made in response to individual enquiries from members of the health professions or appropriate administrative staff relates to unsolicited enquiries only. An unsolicited enquiry is one without any prompting from the company. In answering an unsolicited enquiry a company can offer to provide further information. If the enquirer subsequently requests additional information this can be provided and would be exempt from the Code provided the additional information met the requirements of the exemption. A solicited enquiry would be one where a company invites a person to make a request. For example, material offering further information to readers would be soliciting a request for that information. Placing documents on exhibition stands amounts to an invitation to take them. Neither can take the benefit of this exemption.

Replies intended for use in response to enquiries which are received on a regular basis may be drafted in advance provided that they are used only when they directly and solely relate to the particular enquiry. Documents must not have the appearance of promotional material.

Clause 1.6 Representatives

‘Medical representatives’ and ‘generic sales representatives’ are distinguished in Clause 16.4 relating to examinations for representatives.

Clause 1.7 Applicability of Codes

Pharmaceutical companies must ensure that they comply with all applicable codes, laws and regulations to which they are subject. This is particularly relevant when activities/materials involve more than one country or when

a pharmaceutical company based in one country is involved in activities in another country.

Activities carried out and materials used by a pharmaceutical company located in a European country must comply with the national code of that European country as well as the national code of the country in which the activities take place or the materials are used. Activities carried out and materials used in a European country by a pharmaceutical company located in a country other than a European country must comply with the EFPIA Code as well as the national code of the country in which the activities are carried out and materials are used.

For example a company located in the UK carrying out an activity outside the UK but within Europe, such as in France, must comply with the UK Code and the French Code regardless of whether or not UK health professionals or appropriate administrative staff are involved. Conversely a company located in France carrying out an activity in the UK must comply with the ABPI Code regardless of whether or not UK health professionals or appropriate administrative staff are involved. Details of the various codes can be found at www.efpia.org or www.ifpma.org.

By 'company' is meant any legal entity that organizes or sponsors promotion which takes place within Europe, whether such entity be a parent company (eg the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organization.

In the event of a conflict of requirements the more restrictive requirements would apply.

All international events, that is to say events that take place outside the responsible pharmaceutical company's home country, must be notified in advance to any relevant local subsidiary or local advice taken.

Clause 1.8 Responsible Person

There is an assumption that the responsible person is the managing director or chief executive or equivalent unless other formal arrangements have been made within the company.

Clause 2 Discredit to, and Reduction of Confidence in, the Industry

A ruling of a breach of this clause is a sign of particular censure and is reserved for such circumstances.

Examples of activities that are likely to be in breach of Clause 2 include prejudicing patient safety and/or public health, excessive hospitality, inducements to prescribe, inadequate action leading to a breach of undertaking, promotion prior to the grant of a marketing authorization, conduct of company employees/agents that falls short of competent care and multiple/cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time.

Clause 2 Discredit to, and Reduction of Confidence in, the Industry

Activities or materials associated with promotion must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry.

Clause 3 Marketing Authorization

3.1 A medicine must not be promoted prior to the grant of the marketing authorization which permits its sale or supply.

3.2 The promotion of a medicine must be in accordance with the terms of its marketing authorization and must not be inconsistent with the particulars listed in its summary of product characteristics.

Clause 3 Marketing Authorization

The legitimate exchange of medical and scientific information during the development of a medicine is not prohibited provided that any such information or activity does not constitute promotion which is prohibited under this or any other clause.

Clause 3 Promotion at International Meetings

The promotion of medicines at international meetings held in the UK may on occasion pose certain problems with regard to medicines or indications for medicines which do not have a marketing authorization in the UK although they are so authorized in another major industrialised country.

The display and provision of promotional material for such medicines is permitted at international meetings in the UK provided that the following conditions are met:

- *the meeting must be a truly international meeting of high scientific standing with a significant proportion of attendees from outside the UK*
- *the medicine or indication must be relevant and proportional to the purpose of the meeting*
- *promotional material for a medicine or indication that does not have a UK marketing authorization must be clearly and prominently labelled to that effect*
- *in relation to an unlicensed indication, UK approved prescribing information must be readily available for a medicine authorized in the UK even though it will not refer to the unlicensed indication*
- *the name must be given of at least one major industrialised country (such as EU member states, EFTA countries, Australia, Canada, Israel, Japan, New Zealand, South Africa and the United States of America) in which the medicine or indication is authorized and it must be stated that registration conditions differ from country to country*
- *the material is certified in accordance with Clause 14, except that the signatories need certify only that in their belief the material is a fair and truthful presentation of the facts about the medicine.*

Clause 3.1 Advance Notification of New Products or Product Changes

Health authorities and health boards and their equivalents, trust hospitals and primary care trusts and groups need to estimate their likely budgets two to three years in advance in order to meet Treasury requirements and there is a need for them to receive advance information about the introduction of new medicines, or changes to existing medicines, which may significantly affect their level of expenditure during future years.

At the time this information is required, the medicines concerned (or the changes to them) will not be the subject of marketing authorizations (though applications will often have been made) and it would thus be contrary to the Code for them to be promoted. Information may, however, be provided on the following basis:

Clause 4 Prescribing Information and Other Obligatory Information

4.1 The prescribing information listed in Clause 4.2 must be provided in a clear and legible manner in all promotional material for a medicine except for abbreviated advertisements (see Clause 5) and for promotional aids which meet the requirements of Clause 18.3.

The prescribing information must be positioned for ease of reference and must not be presented in a manner such that the reader has to turn the material round in order to read it, for example by providing it diagonally or around the page borders.

The prescribing information must form part of the promotional material and must not be separate from it.

- i) *the information must relate to:*
 - (a) *a product which contains a new active substance, or*
 - (b) *a product which contains an active substance prepared in a new way, such as by the use of biotechnology, or*
 - (c) *a product which is to have a significant addition to the existing range of authorized indications, or*
 - (d) *a product which has a novel and innovative means of administration*
- ii) *information should be directed to those responsible for making policy decisions on budgets rather than those expected to prescribe*
- iii) *whether or not a new medicine or a change to an existing medicine is the subject of a marketing authorization in the UK must be made clear in advance information*
- iv) *the likely cost and budgetary implications must be indicated and must be such that they will make significant differences to the likely expenditure of health authorities and trust hospitals and the like*
- v) *only factual information must be provided which should be limited to that sufficient to provide an adequate but succinct account of the product's properties; other products should only be mentioned to put the new product into context in the therapeutic area concerned*
- vi) *the information may be attractively presented and printed but should not be in the style of promotional material – product specific logos should be avoided but company logos may be used; the brand name of the product may be included in moderation but it should not be stylized or used to excess*
- vii) *the information provided should not include mock up drafts of either summaries of product characteristics or patient information leaflets*
- viii) *if requested, further information may be supplied or a presentation made.*

Clause 3.2 Unauthorized Indications

The promotion of indications not covered by the marketing authorization for a medicine is prohibited by this clause.

Clause 4.1 Prescribing Information and Summaries of Product Characteristics

Each promotional item for a medicine must be able to stand alone. For example, when a 'Dear Doctor' letter on a medicine is sent in the same envelope as a brochure about the same medicine, each item has to include the prescribing information. It does not suffice to have the prescribing information on only one of the items. The inclusion of a summary of product characteristics moreover does not suffice to conform with the provisions of this clause.

The prescribing information must be consistent with the summary of product characteristics for the medicine.

4.2 The prescribing information consists of the following:

- the name of the medicine (which may be either a brand name or a non-proprietary name)
- a quantitative list of the active ingredients, using approved names where such exist, or other non-proprietary names; alternatively, the non-proprietary name of the product if it is the subject of an accepted monograph
- at least one authorized indication for use consistent with the summary of product characteristics
- a succinct statement of the information in the summary of product characteristics relating to the dosage and method of use relevant to the indications quoted in the advertisement and, where not otherwise obvious, the route of administration
- a succinct statement of common side-effects likely to be encountered in clinical practice, serious side-effects and precautions and contra-indications relevant to the indications in the advertisement, giving, in an abbreviated form, the substance of the relevant information in the summary of product characteristics, together with a statement that prescribers should consult the summary of product characteristics in relation to other side-effects
- any warning issued by the Medicines Commission, the Commission on Human Medicines, the Committee on Safety of Medicines or the licensing authority, which is required to be included in advertisements
- the cost (excluding VAT) of either a specified package of the medicine to which the advertisement relates, or a specified quantity or recommended daily dose, calculated by reference to any specified package of the product, except in the case of advertisements in journals printed in the UK which have more than 15 per cent of their circulation outside the UK and audio-visual advertisements and prescribing information provided in association with them
- the legal classification of the product
- the number of the relevant marketing authorization and the name and address of the holder of the authorization or the name and address of the part of the business responsible for its sale or supply
- the date the prescribing information was drawn up or last revised.

The information specified above in relation to dosage, method of use, side-effects, precautions and contra-indications and any warning which is required to be included in advertisements, must be placed in such a position in the advertisement that its relationship to the claims and indications for the product can be appreciated by the reader.

4.3 In addition, the non-proprietary name of the medicine or a list of the active ingredients using approved names where such exist must appear immediately adjacent to the most prominent display of the brand name in bold type of a size such that a lower case 'x' is no less

Clause 4.1 Legibility of Prescribing Information

The prescribing information is the essential information which must be provided in promotional material. It follows therefore that the information must be given in a clear and legible manner which assists readability.

Legibility is not simply a question of type size. The following recommendations will help to achieve clarity:

- *type size should be such that a lower case letter 'x' is no less than 1 mm in height*
- *lines should be no more than 100 characters in length, including spaces*
- *sufficient space should be allowed between lines to facilitate easy reading*
- *a clear style of type should be used*
- *there should be adequate contrast between the colour of the text and the background*
- *dark print on a light background is preferable*
- *emboldening headings and starting each section on a new line aids legibility.*

Clauses 4.1 and 4.9 Date of Prescribing Information and Material

All prescribing information must include the date that the prescribing information was drawn up or last revised.

In addition, promotional material (other than journal advertising) must include the date that the material as a whole, ie the copy plus the prescribing information, was drawn up or last revised.

Clause 4.1 Electronic Journals

The first part of an advertisement in an electronic journal, such as the banner, is often the only part of the advertisement that is seen by readers. It must therefore include a clear, prominent statement as to where the prescribing information can be found. This should be in the form of a direct link. The first part is often linked to other parts and in such circumstances the linked parts will be considered as one advertisement.

If the first part mentions the product name then this is the most prominent display of the brand name and the non-proprietary name of the medicine or a list of the active ingredients using approved names where such exist must appear immediately adjacent to the most prominent display of the brand name. The size must be such that the information is easily readable. If the product is one that is required to show an inverted black triangle on its promotional material then the black triangle symbol should also appear adjacent to the product name. That is not, however, a requirement of the Code (see supplementary information to Clause 4.3). The requirement of Clause 10 that promotional material and activities should not be disguised should also be borne in mind.

Clause 4.1 Advertisements for Devices

Where an advertisement relates to the merits of a device used for administering medicines, such as an inhaler, which is supplied containing a variety of medicines, the prescribing

than 2mm in height or in type of such a size that the non-proprietary name or list of active ingredients occupies a total area no less than that taken up by the brand name.

4.4 In the case of audio-visual material such as films, video recordings and suchlike and in the case of interactive data systems, the prescribing information may be provided either:

- by way of a document which is made available to all persons to whom the material is shown or sent, or
- by inclusion on the audio-visual recording or in the interactive data system itself.

When the prescribing information is included in an interactive data system instructions for accessing it must be clearly displayed.

4.5 In the case of audio material, ie. material which consists of sound only, the prescribing information must be provided by way of a document which is made available to all persons to whom the material is played or sent.

4.6 In the case of promotional material included on the Internet, there must be a clear, prominent statement as to where the prescribing information can be found.

In the case of an advertisement included in an independently produced electronic journal on the Internet, there must be a clear and prominent statement in the form of a direct link between the first page of the advertisement and the prescribing information.

The non-proprietary name of the medicine or the list of active ingredients, as required by Clause 4.3, must appear immediately adjacent to the brand name at its first appearance in a size such that the information is readily readable.

4.7 In the case of a journal advertisement where the prescribing information appears overleaf, at either the beginning or the end of the advertisement, a reference to where it can be found must appear on the outer edge of the other page of the advertisement in a type size such that a lower case 'x' is no less than 2mm in height.

4.8 In the case of printed promotional material consisting of more than four pages, a clear reference must be given to where the prescribing information can be found.

4.9 Promotional material other than advertisements appearing in professional publications must include the date on which the promotional material was drawn up or last revised.

4.10 All promotional material, other than promotional aids, must include prominent information about adverse event reporting mechanisms.

information for one only need be given if the advertisement makes no reference to any particular medicine.

Full prescribing information must, however, be included in relation to each particular medicine which is referred to.

Clause 4.1 Prescribing Information at Exhibitions

The prescribing information for medicines promoted on posters and exhibition panels at meetings must either be provided on the posters or panels themselves or must be available at the company stand. If the prescribing information is made available at the company stand, this should be referred to on the posters or panels.

Clause 4.3 Non-Proprietary Name

'Immediately adjacent to...' means immediately before, immediately after, immediately above or immediately below.

It should be noted that in a promotional letter the most prominent display of the brand name will usually be that in the letter itself, rather than that in prescribing information provided on the reverse of the letter.

Clause 4.3 Black Triangle Symbol

Certain medicines are required to show an inverted black triangle on their promotional material, other than promotional aids, to denote that special reporting is required in relation to adverse reactions. This is not a Code of Practice or a statutory requirement.

The agreement between the Committee on Safety of Medicines and the ABPI on the use of the black triangle is that:

The symbol should always be black and its size should normally be not less than 5mm per side but with a smaller size of 3mm per side for A5 size advertisements and a larger size of 7.5mm per side for A3 size advertisements:

- *the symbol should appear once and be located adjacent to the most prominent display of the name of the product*
- *no written explanation of the symbol is necessary.*

Clause 4.4 Prescribing Information on Audio-Visual Material

Where prescribing information is shown in the audio-visual material as part of the recording, it must be of sufficient clarity and duration so that it is easily readable. The prescribing information must be an integral part of the advertisement and must appear with it. It is not acceptable for the advertisement and the prescribing information to be separated by any other material.

Clause 4.9 Date Drawn Up or Last Revised

This is in addition to the requirement in Clause 4.2 that the date of the prescribing information be included.

Clause 4.9 Dates on Loose Inserts

A loose insert is not regarded for this purpose as appearing in the professional publication with which it is sent and must therefore bear the date on which it was drawn up or last revised.

Clause 5 Abbreviated Advertisements

5.1 Abbreviated advertisements are advertisements which are exempt from the requirement to include prescribing information for the advertised medicine, provided that they meet with the requirements of this clause.

5.2 Abbreviated advertisements may only appear in professional publications i.e. publications sent or delivered wholly or mainly to members of the health professions and/or appropriate administrative staff. A loose insert in such a publication cannot be an abbreviated advertisement.

Abbreviated advertisements are not permitted in audio-visual material or in interactive data systems or on the Internet, including journals on the Internet.

5.3 Abbreviated advertisements must be no larger than 420 square centimetres in size.

5.4 Abbreviated advertisements must provide the following information in a clear and legible manner:

- the name of the medicine (which may be either a brand name or a non-proprietary name)
- the non-proprietary name of the medicine or a list of the active ingredients using approved names where such exist
- at least one indication for use consistent with the summary of product characteristics
- a statement that prescribers are recommended to consult the summary of product characteristics before prescribing, particularly in relation to side-effects, precautions and contra-indications
- the legal classification of the product
- any warning issued by the Medicines Commission, the Commission on Human Medicines, the Committee on Safety of Medicines or the licensing authority which is required to be included in advertisements
- the name and address of the holder of the marketing authorization or the name and address of the part of the business responsible for its sale or supply

Clause 4.10 Adverse Event Reporting

The requirements of this clause can be met by the inclusion of the statement 'Information about adverse event reporting can be found at www.yellowcard.gov.uk' or similar and 'Adverse events should also be reported to [the relevant pharmaceutical company]'. A telephone number for the relevant department of the company may be included. Text is more likely to be deemed to be prominent if it is presented in a larger type size than that used for the prescribing information.

Clause 5.2 Abbreviated Advertisements – Professional Publications

Abbreviated advertisements are largely restricted to journals and other such professional publications sent or delivered wholly or mainly to members of the health professions etc. A promotional mailing or representative leaflet cannot be an abbreviated advertisement and an abbreviated advertisement cannot appear as part of another promotional item, such as in a brochure consisting of a full advertisement for another of the company's medicines.

Diaries and desk pads bearing a number of advertisements are considered to be professional publications and may include abbreviated advertisements for medicines. Similarly, video programmes and suchlike sent to doctors etc may be considered professional publications and an abbreviated advertisement may be affixed to the side of the video cassette or included on the box containing the video. The prescribing information must, however, be made available for any advertisement for a medicine appearing on audio-visual material or in an interactive data system or on the Internet, including journals on the Internet. Such advertisements cannot be deemed abbreviated advertisements.

Clauses 5.4, 5.5, 5.6 and 5.7 Abbreviated Advertisements – Permitted Information

The contents of abbreviated advertisements are restricted as set out in Clauses 5.4, 5.5, 5.6 and 5.7 and the following information should not therefore be included in abbreviated advertisements:

- marketing authorization numbers
- references
- dosage particulars
- details of pack sizes
- cost.

There may be exceptions to the above if the information provided, for example the cost of the medicine or the frequency of its dosage or its availability as a patient pack, is given as the reason why the medicine is recommended for the indication or indications referred to in the advertisement.

Artwork used in abbreviated advertisements must not convey any information about a medicine which is additional to that permitted under Clauses 5.4, 5.5, 5.6 and 5.7.

- a statement that further information is available on request to the holder of the marketing authorization or that it may be found in the summary of product characteristics.

5.5 In addition, the non-proprietary name of the medicine or a list of the active ingredients using approved names where such exist must appear immediately adjacent to the most prominent display of the brand name in bold type of a size such that a lower case 'x' is no less than 2mm in height or in type of such a size that the non-proprietary name or list of active ingredients occupies a total area no less than that taken up by the brand name.

5.6 In addition, abbreviated advertisements must include prominent information about adverse event reporting mechanisms.

5.7 Abbreviated advertisements may in addition contain a concise statement consistent with the summary of product characteristics, giving the reason why the medicine is recommended for the indication or indications given.

Clause 6 Journal Advertising

6.1 Where the pages of a two page advertisement are not facing, neither must be false or misleading when read in isolation.

6.2 No advertisement taking the form of a loose insert in a journal may consist of more than a single sheet of a size no larger than the page size of the journal itself, printed on one or both sides.

6.3 No issue of a journal may bear advertising for a particular product on more than two pages.

Telephone numbers may be included in abbreviated advertisements.

Clause 5.5 Non-Proprietary Name

'Immediately adjacent to...' means immediately before, immediately after, immediately above or immediately below.

Clause 5.5 Black Triangle Symbol

Certain medicines are required to show an inverted black triangle on their promotional material, other than promotional aids, to denote that special reporting is required in relation to adverse reactions. This is not a Code of Practice or a statutory requirement.

The agreement between the Committee on Safety of Medicines and the ABPI on the use of the black triangle is that:

The symbol should always be black and its size should normally be not less than 5mm per side but with a smaller size of 3mm per side for A5 size advertisements and a larger size of 7.5mm per side for A3 size advertisements:

- *the symbol should appear once and be located adjacent to the most prominent display of the name of the product*
- *no written explanation of the symbol is necessary.*

Clause 5.6 Adverse Event Reporting

The requirements of this clause can be met by the inclusion of the statement 'Information about adverse event reporting can be found at www.yellowcard.gov.uk' or similar and 'Adverse events should also be reported to [the relevant pharmaceutical company]'.

Clause 6 Journal Advertisements

See Clause 4 and in particular Clause 4.7 regarding the requirements for prescribing information in journal advertisements.

A two page journal advertisement is one where the pages follow on without interruption by intervening editorial text or other copy. Thus, for example, promotional material on two successive right hand pages cannot be a single advertisement. Each such page would need to be treated as a separate advertisement for the purposes of prescribing information.

Similarly, if promotional material appears on the outer edges of the left and right hand pages of a double page spread, and the promotional material is separated by intervening editorial matter, then again each page would need to be treated as a separate advertisement.

Clause 6.2 Advertising on the Outside of Journals

Advertising such as cards stapled to a journal and 'wrap-arounds' must not have a greater surface area than that outlined for loose inserts under Clause 6.2.

Clause 7 Information, Claims and Comparisons

7.1 Upon reasonable request, a company must promptly provide members of the health professions and appropriate administrative staff with accurate and relevant information about the medicines which the company markets.

7.2 Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis.

Material must be sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicine.

7.3 A comparison is only permitted in promotional material if:

- it is not misleading
- medicines or services for the same needs or intended for the same purpose are compared
- one or more material, relevant, substantiable and representative features are compared
- no confusion is created between the medicine advertised and that of a competitor or between the advertiser's trade marks, trade names, other distinguishing marks and those of a competitor
- the trade marks, trade names, other distinguishing marks, medicines, services, activities or circumstances of a competitor are not discredited or denigrated
- no unfair advantage is taken of the reputation of a trade mark, trade name or other distinguishing marks of a competitor
- medicines or services are not presented as imitations or replicas of goods or services bearing a competitor's trade mark or trade name.

7.4 Any information, claim or comparison must be capable of substantiation.

7.5 Substantiation for any information, claim or comparison must be provided as soon as possible, and certainly within ten working days, at the request of mem-

Clause 6.3 Limitation on Number of Pages of Advertising

Advertisements taking the form of inserts, whether loose or bound in, count towards the two pages allowed by Clause 6.3. A loose insert printed on both sides counts as two pages.

A summary of product characteristics is permitted as an insert in addition to the two pages of advertising which is allowed.

Inserts and supplements which are not advertisements as such, though they may be regarded as promotional material, for example reports of conference proceedings, are not subject to the restrictions of Clauses 6.2 and 6.3.

Clause 7 General

The application of this clause is not limited to information or claims of a medical or scientific nature. It includes, inter alia, information or claims relating to pricing and market share. Thus, for example, any claim relating to the market share of a product must be substantiated without delay upon request as required under Clause 7.5.

It should be borne in mind that claims in promotional material must be capable of standing alone as regards accuracy etc. In general claims should not be qualified by the use of footnotes and the like.

Clause 7.2 Misleading Information, Claims and Comparisons

The following are areas where particular care should be taken by companies:

- **claims for superior potency in relation to weight** are generally meaningless and best avoided unless they can be linked with some practical advantage, for example, reduction in side-effects or cost of effective dosage
- **the use of data derived from in-vitro studies, studies in healthy volunteers and in animals.** Care must be taken with the use of such data so as not to mislead as to its significance. The extrapolation of such data to the clinical situation should only be made where there is data to show that it is of direct relevance and significance
- **economic evaluation of medicines.** The economic evaluation of medicines is a relatively new science. Care must be taken that any claim involving the economic evaluation of a medicine is borne out by the data available and does not exaggerate its significance

To be acceptable as the basis of promotional claims, the assumptions made in an economic evaluation must be clinically appropriate and consistent with the marketing authorization

Attention is drawn to guidance on good practice in the conduct of economic evaluations of medicines which has been given by the Department of Health and the ABPI and which is available upon request from the Prescription Medicines Code of Practice Authority

- **emerging clinical or scientific opinion.** Where a clinical or scientific issue exists which has not been resolved in favour of one generally accepted viewpoint, particular care must be taken to ensure that the issue is treated in a balanced manner in promotional material

bers of the health professions or appropriate administrative staff. It need not be provided, however, in relation to the validity of indications approved in the marketing authorization.

7.6 When promotional material refers to published studies, clear references must be given.

7.7 When promotional material refers to data on file, the relevant part of this data must be provided without delay at the request of members of the health professions or appropriate administrative staff.

7.8 All artwork including illustrations, graphs and tables must conform to the letter and spirit of the Code and, when taken from published studies, a reference must be given. Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matters with which they deal, and must not be included unless they are relevant to the claims or comparisons being made.

7.9 Information and claims about side-effects must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no side-effects, toxic hazards or risks of addiction or dependency. The word 'safe' must not be used without qualification.

7.10 Promotion must encourage the rational use of a medicine by presenting it objectively and without exaggerating its properties. Exaggerated or all-embracing claims must not be made and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a medicine. Claims should not imply that a medicine or an active ingredient has some special merit, quality or property unless this can be substantiated.

7.11 The word 'new' must not be used to describe any product or presentation which has been generally available, or any therapeutic indication which has been generally promoted, for more than twelve months in the UK.

- **hanging comparisons** whereby a medicine is described as being better or stronger or suchlike without stating that with which the medicine is compared must not be made
- **price comparisons.** Price comparisons, as with any comparison, must be accurate, fair and must not mislead. Valid comparisons can only be made where like is compared with like. It follows therefore that a price comparison should be made on the basis of the equivalent dosage requirement for the same indications. For example, to compare the cost per ml for topical preparations is likely to mislead unless it can be shown that their usage rates are similar or, where this is not possible, for the comparison to be qualified in such a way as to indicate that usage rates may vary
- **statistical information.** Care must be taken to ensure that there is a sound statistical basis for all information, claims and comparisons in promotional material. Differences which do not reach statistical significance must not be presented in such a way as to mislead.

Instances have occurred where claims have been based on published papers in which the arithmetic and/or statistical methodology was incorrect. Accordingly, before statistical information is included in promotional material it must have been subjected to statistical appraisal.

Clause 7.3 Comparisons

The Code does not preclude the use of other companies' brand names when making comparisons.

Clause 7.5 Data from Clinical Trials

Companies must provide substantiation following a request for it, as set out in Clause 7.5. In addition, when data from clinical trials is used companies must ensure that where necessary that data has been registered in accordance with the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases 2005.

Clause 7.6 References

Clause 7.6 applies to references to published material, including the use of quotations, tables, graphs and other illustrative matters.

Clause 7.8 Artwork, Illustrations, Graphs and Tables

Care must be taken to ensure that artwork does not mislead as to the nature of a medicine or any claim or comparison and that it does not detract from any warnings or contra-indications. For example, anatomical drawings used to show results from a study must not exaggerate those results and depictions of children should not be used in relation to products not authorized for use in children in any way which might encourage such use.

Particular care should be taken with graphs and tables to ensure that they do not mislead, for example by their incompleteness or by the use of suppressed zeros or unusual scales. Differences which do not reach statistical significance must not be presented in such a way as to mislead.

Graphs and tables must be adequately labelled so that the information presented can be readily understood. When taken from published studies, the source of the artwork must be given (see also Clause 7.6). If a graph, table or suchlike is taken from a published study it must be faithfully reproduced except where modification is needed in order to comply with the Code. In such circumstances it must be clearly stated that the material has been modified. Any such adaptation must not distort or mislead as to the significance of that graph, table etc. Care should be taken not to mislead when expressing data as percentages; patient numbers should be included wherever possible. It should also be noted that if a table, graph etc in a paper is unacceptable in terms of the requirements of the Code, because, for example, it gives a visually misleading impression as to the data shown, then it must not be used or reproduced in promotional material.

Clause 7.9 Use of the Word 'Safe'

The restrictions on the word 'safe' apply equally to grammatical derivatives of the word such as 'safety'. For example, 'demonstrated safety' or 'proven safety' are prohibited under this clause.

Clause 7.10 Benefit/Risk Profile

The benefit/risk profile of a medicine must be presented in promotional campaigns in such a way as to comply with the Code. Particular attention should be paid to Clauses 7.2, 7.9 and 7.10.

Clause 7.10 Superlatives

Superlatives are those grammatical expressions which denote the highest quality or degree, such as best, strongest, widest etc. A claim that a product was 'the best' treatment for a particular condition, for example, could not be substantiated as there are too many variables to enable such a sweeping claim to be proven. The use of a superlative is acceptable only if it can be substantiated as a simple statement of fact which can be very clearly demonstrated, such as that a particular medicine is the most widely prescribed in the UK for a certain condition, if this is not presented in a way which misleads as to its significance.

Clause 7.10 Use of the Words 'The' and 'Unique'

In certain circumstances the use of the word 'the' can imply a special merit, quality or property for a medicine which is unacceptable under this clause if it cannot be substantiated. For example, a claim that a product is 'The analgesic' implies that it is in effect the best, and might not be acceptable under this clause.

Similarly, great care needs to be taken with the use of the word 'unique'. Although in some circumstances the word unique may be used to describe some clearly defined special feature of a medicine, in many instances it may simply imply a general superiority. In such instances it is not possible to substantiate the claim as the claim itself is so ill defined.

Clause 8 Disparaging References

8.1 The medicines, products and activities of other pharmaceutical companies must not be disparaged.

8.2 The health professions and the clinical and scientific opinions of health professionals must not be disparaged.

Clause 9 High Standards, Format, Suitability and Causing Offence, Sponsorship

9.1 High standards must be maintained at all times.

9.2 All material and activities must recognise the special nature of medicines and the professional standing of the audience to which they are directed and must not be likely to cause offence.

9.3 The name or photograph of a member of a health profession must not be used in any way that is contrary to the conventions of that profession.

9.4 Promotional material must not imitate the devices, copy, slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.

9.5 Promotional material must not include any reference to the Medicines Commission, the Commission on Human Medicines, the Committee on Safety of Medicines, the Medicines and Healthcare products Regulatory Agency, the Medicines Control Agency or the licensing authority, unless this is specifically required by the licensing authority.

9.6 Reproductions of official documents must not be used for promotional purposes unless permission has been given in writing by the appropriate body.

9.7 Extremes of format, size or cost of promotional material must be avoided.

9.8 Postcards, other exposed mailings, envelopes or wrappers must not carry matter which might be regarded as advertising to the general public, contrary to Clause 20.1.

9.9 The telephone, text messages, email, telemessages, facsimile, automated calling systems and other electronic data communications must not be used for promotional purposes, except with the prior permission of the recipient.

Clause 8.1 Disparaging References

Much pharmaceutical advertising contains comparisons with other products and, by the nature of advertising, such comparisons are usually made to show an advantage of the advertised product over its comparator. Provided that such critical references to another company's products are accurate, balanced, fair etc, and can be substantiated, they are acceptable under the Code.

Unjustified knocking copy in which the products or activities of a competitor are unfairly denigrated is prohibited under this clause.

Attention is drawn to the requirements for comparisons set out in Clauses 7.2 to 7.5.

Clauses 9.1 and 9.2 Suitability and Taste

The special nature of medicines and the professional audience to which the material is directed require that the standards set for the promotion of medicines are higher than those which might be acceptable for general commodity advertising.

It follows therefore that certain types, styles and methods of promotion, even where they might be acceptable for the promotion of products other than medicines, are unacceptable. These include:

- *the display of naked or partially naked people for the purpose of attracting attention to the material or the use of sexual imagery for that purpose*
- *'teaser' advertising whereby promotional material is intended to 'tease' the recipient by eliciting an interest in something which will be following or will be available at a later date without providing any actual information about it*
- *the provision of rubber stamps to doctors for use as aids to prescription writing*
- *the provision of private prescription forms preprinted with the name of a medicine.*

Clause 9.7 Extremes of Format, Size or Cost

Particular care needs to be taken in this regard in the first six months following the launch of a medicine to avoid criticism of the industry.

Clause 9.8 Reply Paid Cards

Reply paid cards which are intended to be returned to companies through the post and which relate to a prescription only medicine should not bear both the name of the medicine and information as to its usage but may bear one or the other.

9.10 Material relating to medicines and their uses, whether promotional in nature or not, which is sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that company.

The only exception to this is market research material which need not reveal the name of the company involved but must state that it is sponsored by a pharmaceutical company.

Clause 10 Disguised Promotion

10.1 Promotional material and activities must not be disguised.

10.2 Market research activities, post-marketing surveillance studies, clinical assessments and the like must not be disguised promotion. Post-marketing surveillance studies, clinical assessments and the like must be conducted with a primarily scientific or educational purpose.

Clause 9.10 Declaration of Sponsorship

The declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material are aware of it at the outset.

Clause 9.10 Market Research

Where market research is carried out by an agency on behalf of a pharmaceutical company, the agency must reveal the name of its client to the Prescription Medicines Code of Practice Authority when the Authority requests it to do so. When commissioning market research, a company must take steps to ensure that its identity would be so made known to the Authority should a request for that information be made.

Clause 10.1 Disguised Promotional Material

Promotional material sent in the guise of personal communications, for example by using envelopes or postcards addressed in real or facsimile handwriting is inappropriate. Envelopes must not be used for the dispatch of promotional material if they bear words implying that the contents are non-promotional, for example that the contents provide information relating to safety.

When a company pays for, or otherwise secures or arranges the publication of promotional material in journals, such material must not resemble independent editorial matter. Care must be taken with company sponsored reports of meetings and the like to ensure that they are not disguised promotion. Sponsorship must be declared in accordance with Clause 9.10.

Clause 10.2 Guidelines for Company Sponsored Safety Assessment of Marketed Medicines

Attention is drawn to the Guidelines for Company Sponsored Safety Assessment of Marketed Medicines (SAMM) which have been produced jointly by the ABPI, the British Medical Association, the Committee on Safety of Medicines, the Medicines and Healthcare products Regulatory Agency and the Royal College of General Practitioners. These state that SAMM studies should not be undertaken for the purposes of promotion.

Clause 10.2 Market Research

Market research is the collection and analysis of information and must be unbiased and non-promotional. The use to which the statistics or information is put may be promotional. The two phases must be kept distinct.

Attention is drawn to guidelines – The Legal and Ethical Framework for Healthcare Market Research – produced by the British Healthcare Business Intelligence Association in consultation with the ABPI.

Market research material should be examined to ensure that it does not contravene the Code.

Where market research is carried out by an agency on behalf of a pharmaceutical company, the agency must reveal the name of its client to the Prescription Medicines Code of Practice Authority when the Authority requests it to do so.

Clause 11 Provision of Reprints and the Use of Quotations

11.1 Reprints of articles in journals must not be provided unsolicited unless the articles have been refereed.

11.2 Quotations from medical and scientific literature or from personal communications must be faithfully reproduced (except where adaptation or modification is required in order to comply with the Code) and must accurately reflect the meaning of the author. The precise source of the quotation must be identified.

11.3 Quotations relating to medicines taken from public broadcasts, for example on radio and television, and from private occasions, such as medical conferences or symposia, must not be used without the formal permission of the speaker.

11.4 The utmost care must be taken to avoid ascribing claims or views to authors when these no longer represent the current views of the authors concerned.

Clause 12 Distribution of Promotional Material

12.1 Promotional material should only be sent or distributed to those categories of persons whose need for, or interest in, the particular information can reasonably be assumed.

12.2 Restraint must be exercised on the frequency of distribution and on the volume of promotional material distributed.

12.3 Mailing lists must be kept up-to-date. Requests to be removed from promotional mailing lists must be complied with promptly and no name may be restored except at the addressee's request or with their permission.

When commissioning market research, a company must take steps to ensure that its identity would be so made known to the Authority should a request for that information be made.

Clause 11.1 Provision of Reprints

The provision of an unsolicited reprint of an article about a medicine constitutes promotion of that medicine and all relevant requirements of the Code must therefore be observed. Particular attention must be paid to the requirements of Clause 3.

When providing an unsolicited reprint of an article about a medicine, it should be accompanied by prescribing information.

Clause 11.2 Quotations

Any quotation chosen by a company for use in promotional material must comply with the requirements of the Code itself. For example, to quote from a paper which stated that a certain medicine was 'safe and effective' would not be acceptable even if it was an accurate reflection of the meaning of the author of the paper, as it is prohibited under Clause 7.9 of the Code to state without qualification in promotional material that a medicine is safe.

Quotations can only be adapted or modified in order to comply with the Code. In such circumstances it must be clearly stated that the quotation has been amended.

Care should be taken in quoting from any study or the like to ensure that it does not mislead as to its overall significance. (See Clause 7.2 which prohibits misleading information, claims etc in promotional material). Attention is drawn to the provisions of Clause 7.6 which requires that when promotional material refers to published studies clear references must be given to where they can be found.

Clause 11.4 Current Views of Authors

If there is any doubt as to the current view of an author, companies should check with the author prior to its use in promotional material.

Clause 12.1 Distribution of Promotional Material

Promotional material should be tailored to the audience to whom it is directed. For example, promotional material devised for general practitioners might not be appropriate for hospital doctors and, similarly, material devised for clinicians might not be appropriate for use with National Health Service administrative staff.

Clause 12.2 Frequency of Mailings

The style of mailings is relevant to their acceptability to doctors and criticism of their frequency is most likely to arise where their informational content is limited or where they appear to be elaborate and expensive.

In the first six months following the launch of a new medicine, a health professional may be sent an initial mailing giv-

Clause 13 Scientific Service Responsible for Information

Companies must have a scientific service to compile and collate all information, whether received from medical representatives or from any other source, about the medicines which they market.

Clause 14 Certification

14.1 Promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by two persons on behalf of the company in the manner provided for by this clause. One of the two persons must be a registered medical practitioner or, in the case of a product for dental use only, a registered medical practitioner or a dentist.

A practising UK registered pharmacist working under the direction of a registered medical practitioner may certify certain promotional material instead of a registered medical practitioner. The promotional material that can be so certified is promotional material for products or indications that have been on the market in the UK for more than one year and which is not part of a new and novel promotional campaign. All other material, including that referred to in Clause 14.3 below, must be certified by a registered medical practitioner or, in the case of a product for dental use only, a registered medical practitioner or a dentist.

The second person certifying on behalf of the company must be an appropriately qualified person or senior official of the company or an appropriately qualified person whose services are retained for that purpose.

14.2 All meetings which involve travel outside the UK must be certified in advance in a manner similar to that provided for by Clause 14.1.

14.3 The following must be certified in advance in a manner similar to that provided for by Clause 14.1:

- educational material for the public or patients issued by companies which relates to diseases or medicines but is not intended as promotion for those medicines, including material relating to working with patient organisations as described in Clause 20.3 and its supplementary information

ing detailed information about its use, including, for example, the summary of product characteristics, the public assessment report, the package leaflet and the product monograph, and no more than three other mailings about the medicine.

No more than eight mailings for a particular medicine may be sent to a health professional in a year.

Mailings concerned solely with safety issues can be sent in addition to the above.

Clause 14.1 Certification

An acceptable way to comply with Clause 14.1 is for the final proof to be certified but this is not obligatory provided that that which is certified is in its final form to which no subsequent amendments will be made. Companies may use validated electronic signatures for certifying material. Written copies of certificates and material etc must be preserved in order to comply with Clause 14.6.

All promotional material must be certified in this way including audio and audio-visual material, promotional material on databases, interactive data systems and the Internet, promotional aids and representatives' technical briefing materials.

Account should be taken of the fact that a non-promotional item can be used for a promotional purpose and therefore come within the scope of the Code.

In certifying audio and audio-visual material and promotional material on databases, interactive systems and the Internet, companies must ensure that a written transcript of the material is certified including reproductions of any graphs, tables and the like that appear in it. In the event of a complaint, a copy of the written material will be requested. Alternatively companies may certify material on interactive systems by means of producing an electronic copy, for example on a CD Rom or data stick, if the electronic copy is write protected and unable to be changed.

The guidelines on company procedures relating to the Code which are on page 47 give further information on certification.

See also the supplementary information to Clause 3 on promotion at international conferences regarding the certification of such material.

Clause 14.1 Suitable Qualifications for Signatories

In deciding whether a person can be a nominated signatory, account should be taken of product knowledge, relevant experience both within and outwith the industry, length of service and seniority. In addition signatories must have an up to date, detailed knowledge of the Code. Pharmacists cer-

- non promotional material for patients or health professionals relating to the provision of medical and educational goods and services, including relevant internal company instructions, as described in Clause 18.4 and paragraph 8 of its supplementary information.

14.4 The names of those nominated, together with their qualifications, shall be notified in advance to the Product Information and Advertising Unit of the Post Licensing Division of the Medicines and Healthcare products Regulatory Agency and to the Prescription Medicines Code of Practice Authority. The names and qualifications of designated alternative signatories must also be given. Changes in the names of nominees must be promptly notified.

14.5 The certificate for promotional material must certify that the signatories have examined the final form of the material and that in their belief it is in accordance with the requirements of the relevant advertising regulations and this Code, is not inconsistent with the marketing authorization and the summary of product characteristics and is a fair and truthful presentation of the facts about the medicine.

The certificates for the following must certify that the signatories have examined the final form of the material and that in their belief it complies with the Code:

- educational material for the public or patients issued by companies which relates to diseases or medicines but is not intended as promotion for those medicines, including material relating to working with patient organisations as described in Clause 20.3 and its supplementary information
- non promotional material for patients or health professionals relating to the provision of medical and educational goods and services, including relevant internal company instructions, as described in Clause 18.4 and paragraph 8 of its supplementary information.

Material which is still in use must be recertified at intervals of no more than two years to ensure that it continues to conform with the relevant advertising regulations and the Code.

The certificate for meetings involving travel outside the UK must certify that the signatories have examined all the proposed arrangements for the meeting and that in their belief the arrangements are in accordance with the relevant advertising regulations and the Code.

14.6 Companies shall preserve all certificates. In relation to certificates for promotional material, the material in the form certified and information indicating the persons to whom it was addressed, the method of dissemination and the date of first dissemination must also be preserved. In relation to certificates for meetings involving travel outside the UK, details of the programme, the venue, the reasons for using the venue, the audience, the anticipated and actual costs and the nature of the hospitality and the like must also be preserved.

tifying certain promotional material instead of registered medical practitioners must have not less than one year's experience of working with the product concerned.

Clause 14.1 Joint Ventures and Co-Promotion

In a joint venture in which a third party provides a service on behalf of a number of pharmaceutical companies, the pharmaceutical companies involved are responsible for any activity carried out by that third party on their behalf.

It follows therefore that the pharmaceutical companies involved should be aware of all aspects of the service carried out on their behalf and take this into account when certifying the material or activity involved. Similarly if two or more pharmaceutical companies organise a joint meeting each company should ensure that the arrangements for the meeting are acceptable.

Under co-promotion arrangements whereby companies jointly promote the same medicine and the promotional material bears both company names, each company should certify the promotional material involved as they will be held jointly responsible for it under the Code.

Clause 14.2 Meetings involving Travel outside the UK

When certifying meetings which involve travel outside the UK, the signatories should ensure that all the arrangements are examined, including the programme, the venue, the reasons for using that venue, the intended audience, the anticipated cost and the nature of the hospitality and the like.

Clause 14.3 Examination of Other Material

Other material issued by companies which relates to medicines but which is not intended as promotional material for those medicines per se, such as corporate advertising, press releases, market research material, financial information to inform shareholders, the Stock Exchange and the like, and written responses from medical information departments or similar to unsolicited enquiries from the public etc, should be examined to ensure that it does not contravene the Code or the relevant statutory requirements.

Clause 14.6 Retention of Documentation

Companies should note that the Medicines and Healthcare products Regulatory Agency is entitled to request particulars of an advertisement, including particulars as to the content and form of the advertisement, the method of dissemination and the date of first dissemination, and such a request is not subject to any time limit. This does not apply to the certificates themselves in respect of which the three year limit in Clause 14.6 is applicable.

Companies shall preserve certificates and the relevant accompanying information for not less than three years after the final use of the promotional material or the date of the meeting and produce them on request from the Medicines and Healthcare products Regulatory Agency or the Prescription Medicines Code of Practice Authority.

Clause 15 Representatives

15.1 Representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide full and accurate information about the medicines which they promote.

15.2 Representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties and must comply with all relevant requirements of the Code.

15.3 Representatives must not employ any inducement or subterfuge to gain an interview. No fee should be paid or offered for the grant of an interview.

15.4 Representatives must ensure that the frequency, timing and duration of calls on health professionals, administrative staff in hospitals and health authorities and the like, together with the manner in which they are made, do not cause inconvenience. The wishes of individuals on whom representatives wish to call and the arrangements in force at any particular establishment, must be observed.

15.5 In an interview, or when seeking an appointment for one, representatives must at the outset take reasonable steps to ensure that they do not mislead as to their identity or that of the company they represent.

15.6 Representatives must transmit forthwith to the scientific service referred to in Clause 13 any information which they receive in relation to the use of the medicines which they promote, particularly reports of side-effects.

15.7 Representatives must be paid a fixed basic salary and any addition proportional to sales of medicines must not constitute an undue proportion of their remuneration.

15.8 Representatives must provide, or have available to provide if requested, a copy of the summary of product characteristics for each medicine which they are to promote.

15.9 Companies must prepare detailed briefing material for medical representatives on the technical aspects of each medicine which they will promote. A copy of such material must be made available to the Medicines and Healthcare products Regulatory Agency and the Prescription Medicines Code of Practice Authority on request. Briefing material must comply with the relevant requirements of the Code and, in particular, is subject to the certification requirements of Clause 14.

Clause 15 Representatives

All provisions in the Code relating to the need for accuracy, balance, fairness, good taste etc apply equally to oral representations as well as to printed material. Representatives must not make claims or comparisons which are in any way inaccurate, misleading, disparaging, in poor taste etc, or which are outside the terms of the marketing authorization for the medicine or are inconsistent with the summary of product characteristics. Indications for which the medicine does not have a marketing authorization must not be promoted.

Attention is drawn to the provisions of Clause 9.9 which prohibit the use of the telephone, text messages, email, telemessages and facsimile etc for promotional purposes, except with the prior permission of the recipient.

Clause 15 Contract Representatives

Companies employing or using contract representatives are responsible for their conduct and must ensure that they comply with the provisions of this and all other relevant clauses in the Code, and in particular the training requirements under Clauses 15.1, 16.1, 16.3 and 16.4.

Clause 15.3 Hospitality and Payments for Meetings

Attention is drawn to the requirements of Clauses 18 and 19 which prohibit the provision of any financial inducement for the purposes of sales promotion and require that any hospitality provided is secondary to the purpose of a meeting, is not out of proportion to the occasion and does not extend beyond members of the health professions or appropriate administrative staff.

Meetings organised for groups of doctors, other health professionals and/or appropriate administrative staff which are wholly or mainly of a social or sporting nature are unacceptable.

Representatives organising meetings are permitted to provide appropriate hospitality and/or to meet any reasonable, actual costs which may have been incurred. For example, if the refreshments have been organised and paid for by a medical practice the cost may be reimbursed as long as it is reasonable in relation to what was provided and the refreshments themselves were appropriate for the occasion.

Donations in lieu of hospitality are unacceptable as they are inducements for the purpose of holding a meeting. If hospitality is not required at a meeting there is no obligation or right to provide some benefit of an equivalent value.

Briefing material must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.

15.10 Companies are responsible for the activities of their representatives if these are within the scope of their employment even if they are acting contrary to the instructions which they have been given.

Clause 15.3 Donations to Charities

Donations to charities in return for representatives gaining interviews are prohibited under Clause 15.3.

Clause 15.3 Items Delivered by Representatives

Reply paid cards which refer to representatives delivering items which have been offered to health professionals or appropriate administrative staff should explain that there is no obligation to grant the representative an interview when the item is delivered. This is to avoid the impression that there is such an obligation, which would be contrary to Clause 15.3 which prohibits the use of any inducement to gain an interview.

Clause 15.3 General Medical Council

The General Medical Council is the regulatory body for the medical profession and is responsible for giving guidance on standards of professional conduct and on medical ethics. In its guidance, the Council advises doctors that 'You must act in your patients' best interests when making referrals and providing or arranging treatment or care. So you must not ask for or accept any inducement, gift or hospitality which may affect or be seen to affect your judgement'.

Clause 15.4 Frequency and Manner of Calls on Doctors and Other Prescribers

The number of calls made on a doctor or other prescriber and the intervals between successive visits are relevant to the determination of frequency.

Companies should arrange that intervals between visits do not cause inconvenience. The number of calls made on a doctor or other prescriber by a representative each year should not normally exceed three on average. This does not include the following which may be additional to those three visits:

- *attendance at group meetings, including audio-visual presentations and the like*
- *a visit which is requested by a doctor or other prescriber or a call which is made in order to respond to a specific enquiry*
- *a visit to follow up a report of an adverse reaction.*

Representatives must always endeavour to treat prescribers' time with respect and give them no cause to believe that their time might have been wasted. If for any unavoidable reasons, an appointment cannot be kept, the longest possible notice must be given.

Clause 15.8 Provision of Summary of Product Characteristics

If discussion on a medicine is initiated by the person or persons on whom a representative calls, the representative is not obliged to have available the information on that medicine referred to in this clause.

Clause 15.9 Briefing Material

The detailed briefing material referred to in this clause consists of both the training material used to instruct medical representatives about a medicine and the instructions given to them as to how the product should be promoted.

Clause 16 Training

16.1 All relevant personnel including representatives and members of staff (including persons retained by way of contract with third parties) concerned in any way with the preparation or approval of promotional material or of information to be provided to members of the UK health professions and to appropriate administrative staff or of information to be provided to the public and recognised patient organisations must be fully conversant with the requirements of the Code and the relevant laws and regulations.

16.2 All personnel (including persons retained by way of contract with third parties) must be fully conversant with pharmacovigilance requirements relevant to their work and this must be documented.

16.3 Representatives must pass the appropriate ABPI representatives examination, as specified in Clause 16.4. They must be entered for the appropriate examination within their first year of such employment. Prior to passing the appropriate examination, they may be engaged in such employment for no more than two years, whether continuous or otherwise.

16.4 The Medical Representatives Examination is appropriate for, and must be taken by, representatives whose duties comprise or include one or both of:

- calling upon doctors and/or dentists and/or other prescribers
- the promotion of medicines on the basis, *inter alia*, of their particular therapeutic properties.

The Generic Sales Representatives Examination is appropriate for, and must be taken by, representatives who promote medicines primarily on the basis of price, quality and availability.

16.5 Persons who have passed the Medical Representatives Examination whose duties change so as to become those specified in Clause 16.4 as being appropriate to the Generic Sales Representatives Examination are exempt from the need to take that examination.

Persons who have passed the Generic Sales Representatives Examination whose duties change so as to become those specified in Clause 16.4 as being appropriate to the Medical Representatives Examination must pass that examination within two years of their change of duties.

16.6 Details of the numbers of medical and generic sales representatives who have passed the respective examinations above, together with the examination status of others, must be provided to the Prescription Medicines Code of Practice Authority on request.

Clause 16.1 Training

Extensive in house training on the Code is carried out by companies and by the Prescription Medicines Code of Practice Authority.

In addition, the Authority runs seminars on the Code which are open to all companies and personnel from advertising agencies, public relations agencies and the like which act for the pharmaceutical industry. Details of these seminars can be obtained from the Authority.

Clause 16.3 Time Allowed to Pass Examination

Prior to passing the appropriate ABPI examination, representatives may be engaged in such employment for no more than two years, whether continuous or otherwise and irrespective of whether with one company or with more than one company. A representative cannot, for example, do eighteen months with one company and eighteen months with another and so on, thus avoiding the examination.

In the event of extenuating circumstances, such as prolonged illness or no or inadequate opportunity to take the examination, the Director of the Prescription Medicines Code of Practice Authority may agree to the continued employment of a person as a representative past the end of the two year period, subject to the representative passing the examination within a reasonable time.

Service as a representative prior to 1 January 2006 by persons who were exempt from taking the appropriate examination by virtue of Clause 16.4 of the 2003 edition of the Code does not count towards the two year limit on employment as a representative prior to passing the appropriate examination. In order to comply with Clause 16.3 such persons must be entered for the appropriate examination before 1 January 2007 and must pass it before 1 January 2008.

Clause 16.4 Medical Representatives and Generic Sales Representatives

The ABPI examinations for medical representatives and generic sales representatives are based on a syllabus published by the ABPI which covers, as appropriate, subjects such as body systems, disease processes and pharmacology, the classification of medicines and pharmaceutical technology. Information on the National Health Service and pharmaceutical industry forms an additional core part of the syllabus. The syllabus is complementary to, and may be incorporated within, the company's induction training which is provided to representatives as a pre-requisite to carrying out their function.

Clause 17 Provision of Medicines and Samples

17.1 Samples of a product may be provided only to a health professional qualified to prescribe that product. They must not be provided to administrative staff.

17.2 No more than ten samples of a particular medicine may be provided to an individual health professional during the course of a year.

17.3 Samples may only be supplied in response to written requests which have been signed and dated.

17.4 A sample of a medicine must be no larger than the smallest presentation of the medicine on the market in the UK.

17.5 Each sample must be marked 'free medical sample – not for resale' or words to that effect and must be accompanied by a copy of the summary of product characteristics.

17.6 The provision of samples is not permitted for any medicine which contains a substance listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the medicine is not a preparation listed in Schedule III to that Convention) or a substance listed in any of Schedules I to IV of the Psychotropic Substances Convention (where the medicine is not a preparation which may be exempted from measures of control in accordance with Paragraphs 2 and 3 of Article 3 of that Convention).

17.7 Samples distributed by representatives must be handed direct to the health professionals requesting them or persons authorized to receive them on their behalf.

17.8 The provision of medicines and samples in hospitals must comply with individual hospital requirements.

17.9 Companies must have adequate systems of control and accountability for samples which they distribute and for all medicines handled by representatives.

17.10 Medicines which are sent by post must be packed so as to be reasonably secure against being opened by young children. No unsolicited medicine must be sent through the post.

17.11 Medicines may not be sold or supplied to members of the general public for promotional purposes.

Clause 17 Definition of Sample

A sample is a small supply of a medicine provided to health professionals so that they may familiarise themselves with it and acquire experience in dealing with it. A sample of a medicine may be provided only to a health professional qualified to prescribe that particular medicine.

A small sample which is provided only for identification or similar purposes and which is not intended to be used in treatment may be provided to any health professional but is otherwise subject to the requirements of Clause 17.

Titration packs, free goods and bonus stock provided to pharmacists and others are not samples. Neither are starter packs classified as samples. This is because they are not for the purposes described above.

Starter packs are small packs designed to provide sufficient medicine for a primary care prescriber to initiate treatment in such circumstances as a call out in the night or in other instances where there might be some undesirable or unavoidable delay in having a prescription dispensed. It follows from this that the types of medicines for which starter packs are appropriate are limited to those where immediate commencement of treatment is necessary or desirable, such as analgesics and antibiotics. Starter packs are not samples and should not be labelled as such. The quantity of medicine in a starter pack should be modest, only being sufficient to tide a patient over until their prescription can be dispensed.

Titration packs are packs containing various strengths of a medicine for the purpose of establishing a patient on an effective dose.

Clause 17.3 Sample Requests

This clause does not preclude the provision of a preprinted sample request form bearing the name of the product for signing and dating by the applicant.

All signed and dated written requests for samples should be retained for not less than one year.

Clause 17.9 Control and Accountability

Companies should ensure that their systems of control and accountability relating to medicines held by representatives cover such matters as the security of delivery to them, the security of medicines held by them, the audit of stocks held by them, including expiry dates, and the return to the companies of medicines no longer to be held by representatives.

Clause 18 Gifts, Inducements, Promotional Aids and the Provision of Medical and Educational Goods and Services

18.1 No gift, benefit in kind or pecuniary advantage shall be offered or given to members of the health professions or to administrative staff as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, subject to the provisions of Clause 18.2.

18.2 Promotional aids, whether related to a particular product or of general utility, may be distributed to members of the health professions and to appropriate administrative staff, provided that the promotional aids are inexpensive and relevant to the practice of their profession or employment.

18.3 The prescribing information for a medicine as required under Clause 4 does not have to be included on a promotional aid if the promotional aid includes no more than the following about the medicine:

- the brand name or the non-proprietary name of the medicine
- an indication that the name of the medicine is a trade mark
- the name of the company responsible for marketing the product.

18.4 Medical and educational goods and services which enhance patient care, or benefit the NHS and maintain patient care, can be provided subject to the provisions of Clause 18.1. Medical and educational goods and services must not bear the name of any medicine.

Clause 18.1 General Medical Council

The General Medical Council is the regulatory body for the medical profession and is responsible for giving guidance on standards of professional conduct and on medical ethics. In its guidance, the Council advises doctors that 'You must act in your patients' best interests when making referrals and providing or arranging treatment or care. So you must not ask for or accept any inducement, gift or hospitality which may affect or be seen to affect your judgement'.

Clause 18.1 Terms of Trade

Measures or trade practices relating to prices, margins and discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993 are outside the scope of the Code (see Clause 1.2) and are excluded from the provisions of this clause. Other trade practices are subject to the Code. The terms 'prices', 'margins' and 'discounts' are primarily financial terms.

Schemes which enable health professionals to obtain personal benefits, for example gift vouchers for high street stores, in relation to the purchase of medicines are unacceptable even if they are presented as alternatives to financial discounts.

The Royal Pharmaceutical Society of Great Britain has issued guidance in relation to the acceptance of gifts and inducements to prescribe or supply. The Society states that pharmacists accepting items such as gift vouchers, bonus points, discount holidays, sports equipment etc would be in breach of UK law and advises pharmacists not to participate in such offers.

Clause 18.1 Package Deals

Clause 18.1 does not prevent the offer of package deals whereby the purchaser of particular medicines receives with them other associated benefits, such as apparatus for administration, provided that the transaction as a whole is fair and reasonable and the associated benefits are relevant to the medicines involved.

Clause 18.1 Donations to Charities

Donations to charities made by companies in return for health professionals' attendance at company stands at meetings are not unacceptable under this clause provided that the level of donation for each individual is modest, the money is for a reputable charity and any action required of the health professional is not inappropriate. Any donation to a charity must not constitute a payment that would otherwise be unacceptable under the Code. For example, it would not be acceptable for a representative to pay into a practice equipment fund set up as a charity as this would be a financial inducement prohibited under Clause 18.1. Donations to charities in return for representatives gaining interviews are also prohibited under Clause 15.3 of the Code.

Any offer by a company of a donation to a charity which is conditional upon some action by a health professional must not place undue pressure on the health professional to fulfil that condition. At all times the provisions of Clauses 2 and 9.1 must be kept in mind.

Clause 18.2 Gifts

Items provided on long term or permanent loan to a doctor or other prescriber or a practice are regarded as gifts and are subject to the requirements of this clause.

Promotional aids must be inexpensive and relevant to the recipients' work and are more likely to be acceptable if they benefit patient care. An 'inexpensive' promotional aid means one which has cost the donor company no more than £6, excluding VAT. The perceived value to the recipient must be similar.

Items for the personal benefit of health professionals or appropriate administrative staff must not be offered or provided.

Items of general utility which are acceptable promotional aids for health professionals as being inexpensive and of relevance to their work include stationery items, such as computer accessories for business use, pens, pads, diaries and calendars and clinical items, such as nail brushes, surgical gloves, tongue depressors, tissues and peak flow meters. It is permissible to give a coffee mug.

Items which are for use in the home or car are unacceptable. Examples of unacceptable items include table mats, coasters, clocks, desk thermometers, fire extinguishers, rugs, thermos flasks, coffee pots, tea pots, lamps, travel adaptors, toolboxes, umbrellas, neck cushions, plant seeds, road atlases and compact discs of music.

Names of medicines should not be used on promotional aids when it would be inappropriate to do so, for example when it might mislead as to the nature of the item.

Certain independently produced medical/educational publications such as textbooks have been held to be acceptable gifts under Clause 18.2. The content of publications used in this way has to be considered carefully and must comply with the Code as regards any references to the donor's or competitors' products. It might be possible to give certain medical/educational publications in accordance with Clause 18.4 – Provision of Medical and Educational Goods and Services.

Clause 18.2 Competitions and Quizzes

The use of competitions, quizzes and suchlike, and the giving of prizes, are unacceptable methods of promotion.

Clause 18.2 Gifts To or for Use by Patients

Some items distributed as promotional aids are intended for use by patients and these are not generally unacceptable provided that they meet the requirements of Clause 18.2; for example, puzzles and toys for a young child to play with during a visit to the doctor.

Other items which may be made available to patients, for example by completing a request card enclosed with a medicine, should meet the relevant principles set out in Clause 18.2, that is they should be inexpensive and related to either the condition under treatment or general health. Care must be taken that any such activity meets all the requirements of the Code and in particular Clause 20.

No gift or promotional aid for use by patients must be given for the purpose of encouraging patients to request a particular medicine.

Clause 18.3 Promotional Aids – Name of the Medicine

A promotional aid may bear the names of more than one medicine.

Clause 18.3 Prescribing Information on Note Pads and Calendars

If a promotional aid consists of a note pad or calendar in which the individual pages bear advertising material, there is no need for the individual pages to comply with Clause 4 provided that the information required by that clause is given elsewhere; for example, on the cover.

Clause 18.4 Provision of Medical and Educational Goods and Services

Clauses 18.1 and 18.4 do not prevent the provision of medical and educational goods and services. In order to comply with the Code such goods and services must be in the interests of patients or benefit the NHS whilst maintaining patient care.

Medical and educational goods and services may bear a corporate name. The involvement of a pharmaceutical company in such activities must be made clear to relevant health professionals and/or administrative staff receiving the service. In addition the involvement of a pharmaceutical company in therapy review services should be made clear to patients. However, if there are no materials for patients this would be a matter for the relevant health professional. If there are materials for patients the requirements for declaration of sponsorship set out in Clause 9.10 would apply.

The following guidance is intended to assist companies in relation to medical and educational goods and services.

1(i) The role of medical/generic representatives in relation to the provision of goods and services supplied in accordance with Clauses 18.1 and 18.4 needs to be in accordance with the principles set out below. In this context companies should consider using staff other than medical/generic representatives.

(ii) If medical/generic representatives provide, deliver or demonstrate medical and educational goods and services then this must not be linked in any way to the promotion of products.

In order to comply with this stipulation the representative must not carry out both activities at the same visit. Representatives may introduce a service by means of a brief description and/or delivering materials but may not instigate a detailed discussion about the service at the same time as a call at which products are promoted.

(iii) The acceptability of the role of medical/generic representatives will depend on the nature of the goods and services provided and the method of provision.

(iv) The nature of the service provider, the person associated with the provision of medical and educational goods and services, is important ie is the service provider a medical/generic representative or is the service provider some other appropriately qualified person, such as a sponsored registered nurse? If the goods and services require patient contact, for example either directly or by identification of patients from patient records and the like, then medical/generic representatives must not be involved. Only an appropriately qualified person, for example a sponsored registered nurse, not employed as a medical/generic representative, may undertake activities relating to patient contact and/or patient identification. Medical/generic representatives could provide administrative support in relation to the provision of a screening service, but must not be present during the actual screening and must not discuss or help interpret individual clinical findings.

(v) Neither the company nor its medical/generic representatives may be given access to data/records that could identify, or could be linked to, particular patients.

(vi) Sponsored health professionals should not be involved in the promotion of specific products. Registered nurses, midwives and health visitors are required to comply with the Nursing & Midwifery Council Code of professional conduct. That Code requires, *inter alia*, that registration status is not used in the promotion of commercial products or services.

2 The remuneration of those not employed as medical/generic representatives but who are sponsored or employed as service providers in relation to the provision of medical and educational goods and services must not be linked to sales in any particular territory or place or to sales of a specific product or products and, in particular, may not include a bonus scheme linked to such sales. Bonus schemes linked to a company's overall national performance, or to the level of service provided, may be acceptable.

3 Companies must ensure that patient confidentiality is maintained at all times and that data protection legislation is complied with.

4 Service providers must operate to detailed written instructions provided by the company. These should be similar to the briefing material for representatives as referred to in Clause 15.9. The written instructions should set out the role of the service provider and should cover patient confidentiality issues. Instructions on how the recipients are to be informed etc should be included. The written instructions must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.

5 Service providers must abide by the principle set out in Clause 15.5 that in an interview, or when seeking an appointment, reasonable steps must be taken to ensure that they do not mislead as to their identity or that of the company they represent.

6 A recipient of a service must be provided with a written protocol to avoid misunderstandings as to what the recipient has agreed. The identity of the sponsoring pharmaceutical company must be given. For example, a general practitioner allowing a sponsored registered nurse access to patient records should be informed in writing of any data to be extracted and the use to which those data will be put.

7 Any printed material designed for use in relation to the provision of medical and educational goods and services must be non-promotional. It is not acceptable for such materials to promote the prescription, supply, sale or administration of the sponsoring company's medicines: Nor is it acceptable for materials to criticise competitor products as this might be seen as promotional. All printed materials must identify the sponsoring pharmaceutical company.

8 Material relating to the provision of medical and educational goods and services, such as internal instructions, external instructions, the written protocol for recipients and other printed material, including material relating to therapy reviews, etc, must be certified by the Code of Practice signatories within companies to ensure that the requirements of the Code are met as required by Clause 14.3.

A copy of the materials must be made available to the Prescription Medicines Code of Practice Authority on request.

9 Companies are recommended to inform relevant parties such as NHS trusts, health authorities, health boards and primary care organisations of their activities where appropriate. This is particularly recommended where companies are proposing to provide medical and educational goods and services which would have budgetary implications for the parties involved. For example the provision of a screening service for a limited period might mean that funds would have to be found in the future when company sponsorship stopped. Another example might be the provision of diagnostic or laboratory services and the like, which the NHS trust, health authority, health board or primary care organisation would normally be expected to provide.

Clause 18.4 Switch and Therapy Review Programmes

Clauses 18.1 and 18.4 prohibit switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a patient's medicine is simply changed to another. For example it would be unacceptable if patients on medicine A were changed to medicine B, without any clinical assessment, at the expense of a pharmaceutical company promoting either or both medicines. It would be acceptable for a company to promote a simple switch from one product to another but not to assist a health professional in implementing that switch even if assistance was by means of a third party such as a sponsored nurse or similar. Such arrangements are seen as companies in effect paying for prescriptions and are unacceptable.

A therapeutic review is different to a switch service. A therapeutic review which aims to ensure that patients receive optimal treatment following a clinical assessment is a legitimate activity for a pharmaceutical company to support and/or assist. The result of such clinical assessments might require, among other things, possible changes of treatment including changes of dose or medicine or cessation of treatment. A genuine therapeutic review should include a comprehensive range of relevant treatment choices, including non-medicinal choices, for the health professional and should not be limited to the medicines of the sponsoring pharmaceutical company. The arrangements for therapeutic review

Clause 19 Meetings and Hospitality

19.1 Companies must not provide hospitality to members of the health professions and appropriate administrative staff except in association with scientific meetings, promotional meetings, scientific congresses and other such meetings. Meetings must be held in appropriate venues conducive to the main purpose of the event. Hospitality must be strictly limited to the main purpose of the event and must be secondary to the purpose of the meeting ie subsistence only. The level of subsistence offered must be appropriate and not out of proportion to the occasion. The costs involved must not exceed that level which the recipients would normally adopt when paying for themselves. It must not extend beyond members of the health professions or appropriate administrative staff.

19.2 Payments may not be made to doctors or groups of doctors or to other prescribers, either directly or indirectly, for rental for rooms to be used for meetings.

19.3 When meetings are sponsored by pharmaceutical companies, that fact must be disclosed in all of the papers relating to the meetings and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset.

must enhance patient care, or benefit the NHS and maintain patient care, and must otherwise be in accordance with Clause 18.4 and the supplementary information on the provision of medical and educational goods and services. The decision to change or commence treatment must be made for each individual patient by the prescriber and every decision to change an individual patient's treatment must be documented with evidence that it was made on rational grounds.

Clause 19.1 Meetings and Hospitality

The provision of hospitality is limited to refreshments/subsistence (meals and drinks), accommodation, genuine registration fees and the payment of reasonable travel costs which a company may provide to sponsor a delegate to attend a meeting. The payment of travel expenses and the like for persons accompanying the delegate is not permitted. Funding must not be offered or provided to compensate merely for the time spent by health professionals in attending meetings. The payment of reasonable honoraria and reimbursement of out of pocket expenses, including travel, for speakers, advisory board members and the providers of other professional services, is permissible. The arrangements for meetings must comply with Clause 19.1 with regard to hospitality and venues.

Companies should only offer or provide economy air travel to delegates sponsored to attend meetings. Delegates may of course organise and pay at their own expense the genuine difference between economy travel and business class or first class.

Pharmaceutical companies may appropriately sponsor a wide range of meetings. These range from small lunchtime audio-visual presentations in a group practice, hospital meetings and meetings at postgraduate education centres, launch meetings for new products, management training courses, meetings of clinical trialists, patient support group meetings, satellite symposia through to large international meetings organised by independent bodies with sponsorship from pharmaceutical companies.

With any meeting, certain basic principles apply:

- *the meeting must have a clear educational content*
- *the venue must be appropriate and conducive to the main purpose of the meeting; lavish or deluxe venues must not be used and companies should avoid using venues that are renowned for their entertainment facilities*
- *the subsistence associated with the meeting must be secondary to the nature of the meeting, must be appropriate and not out of proportion to the occasion and*
- *any hospitality provided must not extend to a spouse or other such person unless that person is a member of the health professions or appropriate administrative staff and qualifies as a proper delegate or participant at the meeting in their own right*
- *spouses and other accompanying persons, unless qualified as above, may not attend the actual meeting and may not receive any associated hospitality at the company's expense; the entire costs which their presence involves are the responsibility of those they accompany.*

Administrative staff may be invited to meetings where appropriate. For example, receptionists might be invited to a meeting in a general practice when the subject matter related to practice administration.

A useful criterion in determining whether the arrangements for any meeting are acceptable is to apply the question 'would you and your company be willing to have these arrangements generally known?' The impression that is created by the arrangements for any meeting must always be kept in mind.

Meetings organised for groups of doctors, other health professionals and/or for administrative staff which are wholly or mainly of a social or sporting nature are unacceptable.

Meetings organised by pharmaceutical companies which involve UK health professionals at venues outside the UK are not necessarily unacceptable. There have, however, to be valid and cogent reasons for holding meetings at such venues. These are that most of the invitees are from outside the UK and, given their countries of origin, it makes greater logistical sense to hold the meeting outside the UK or, given the location of the relevant resource or expertise that is the object or subject matter of the meeting, it makes greater logistical sense to hold the meeting outside the UK. As with meetings held in the UK, in determining whether such a meeting is acceptable or not, consideration must also be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, subsistence provided and the like. As with any meeting it should be the programme that attracts delegates and not the associated hospitality or venue.

The requirements of the Code do not apply to the provision of hospitality other than to those referred to in Clause 19.1 and in the supplementary information to Clauses 20.2 and 20.3.

Clause 19.1 Certification of Meetings

Pharmaceutical companies must ensure that all meetings which are planned are checked to see that they comply with the Code. Companies must have a written document that sets out their policies on meetings and hospitality and the associated allowable expenditure. In addition, meetings which involve travel outside the UK must be formally certified as set out in Clause 14.2 of the Code.

Clause 19.1 General Medical Council

The General Medical Council is the regulatory body for the medical profession and is responsible for giving guidance on standards of professional conduct and on medical ethics. In its guidance, the Council advises doctors that 'You must act in your patients' best interests when making referrals and providing or arranging treatment or care. So you must not ask for or accept any inducement, gift or hospitality which may affect or be seen to affect your judgement'.

Clause 19.1 Continuing Professional Development (CPD) Meetings and Courses

The provisions of this and all other relevant clauses in the Code apply equally to meetings and courses organised or sponsored

by pharmaceutical companies which are continuing professional development (CPD) approved, such as postgraduate education allowance (PGEA) approved meetings and courses. The fact that a meeting or course has CPD approval does not mean that the arrangements are automatically acceptable under the Code. The relevant provisions of the Code and, in particular, those relating to hospitality, must be observed.

Clause 19.2 Payment of Room Rental

This provision does not preclude the payment of room rental to postgraduate medical centres and the like.

Payment of room rental to doctors or groups of doctors or to other prescribers is not permissible even if such payment is made to equipment funds or patients' comforts funds and the like or to charities or companies.

Clause 19.3 Sponsorship and Reports of Meetings

Attention is drawn to Clause 9.10 which requires that all material relating to medicines and their uses, whether promotional or not, which is sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that company.

It should be noted that where companies are involved in the sponsorship and/or distribution of reports on meetings or symposia etc, these reports may constitute promotional material and thus be fully subject to the requirements of the Code.

Clause 20 Relations with the General Public and the Media

20.1 Prescription only medicines must not be advertised to the general public. This prohibition does not apply to vaccination campaigns carried out by companies and approved by the health ministers.

20.2 Information about prescription only medicines which is made available to the public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product.

Statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine.

20.3 Pharmaceutical companies can work with patient organisations but when doing so must ensure that the involvement of the company is made clear and that all of the arrangements comply with the Code. This includes the need to declare sponsorship (Clause 9.10) and the prohibition on advertising prescription only medicines to the public (Clause 20.1). The requirements of Clause 19, which covers meetings for health professionals and appropriate administrative staff, also apply to pharmaceutical companies supporting patient organisation meetings.

20.4 Requests from individual members of the public for advice on personal medical matters must be refused and the enquirer recommended to consult his or her own doctor or other prescriber or other health professional.

20.5 The introduction of a new medicine must not be made known to the public until reasonable steps have been taken to inform the medical and pharmaceutical professions of its availability.

20.6 Companies are responsible for information about their products which is issued by their public relations agencies.

Clause 20.1 Advertising of Medicines to the General Public

The advertising of prescription only medicines to the public is also prohibited by the Advertising Regulations.

The promotion of medicines to the public for self medication purposes is covered by the Code of Standards of Advertising Practice for Over-the-Counter Medicines of the Proprietary Association of Great Britain (PAGB).

Methods of sale of medicines through pharmacies are also covered by the Code of Ethics and Standards of the Royal Pharmaceutical Society of Great Britain.

Clause 20.2 Information to the Public

This clause allows for the provision of non-promotional information about prescription only medicines to the public either in response to a direct enquiry from an individual, including enquiries from journalists, or by dissemination of such information via press conferences, press announcements, television and radio reports, public relations activities and the like. It also includes information provided by means of posters distributed for display in surgery waiting rooms etc and reference information made available by companies on their websites or otherwise as a resource for members of the public.

Any information so provided must observe the principles set out in this clause; that is, it should be factual, balanced and must not be made for the purpose of encouraging members of the public to ask their doctors or other prescribers to prescribe a specific prescription only medicine. It must not constitute the advertising of prescription only medicines to the public prohibited under Clause 20.1. The provisions of Clause 20.4 must be observed if an enquiry is from an individual member of the public.

Information to the public falls into one of three categories depending on its purpose, how it is supplied and how the public is made aware of the information.

Proactive information is supplied to the public without a direct request. This includes booklets on diseases and/or medicines supplied directly or via a health professional, press releases, briefings, conferences, mailings to patient organisations and disease awareness advertising.

Reference information is intended to provide a comprehensive up-to-date resource that companies should make available on their websites or by way of a link from their website or by some other means. The primary purpose of reference information is to be a library resource for members of the public giving information relating to prescription only medicines which have marketing authorizations. Pharmaceutical companies are not obliged to provide reference information but it is considered good practice to provide as a minimum the regulatory information comprising the summary of product characteristics (SPC), the package information leaflet (PIL) and the public assessment report (PAR) (UK or European) where such a document exists. Reference information may also include the registration studies used for marketing authorization applications and variations and any other studies published or not including those referred to in the

SPC, PIL, EPAR or UKPAR or available on clinical trial databases. Reference information may also include material supplied for health technology assessments to bodies such as the National Institute for Health and Clinical Excellence (NICE), the All Wales Medicines Strategy Group (AWMSG) and the Scottish Medicines Consortium (SMC).

Reference information may also include medicine guides where available, studies (published or not), information about diseases and information about specific medicines etc.

Where companies decide to make reference information available this must represent fairly the current body of evidence relating to a medicine and its benefit/risk profile.

Reactive information is supplied to the public in response to a direct request and must be limited to that information necessary to respond to the request.

It is good practice to include the summary of product characteristics with a press release or press pack relating to a medicine. Companies should also consider including references to other credible sources of information about a condition or a medicine.

Particular care must be taken in responding to approaches from the media to ensure that the provisions of this clause are upheld.

In the event of a complaint which relates to the provisions of this clause, companies will be asked to provide copies of any information supplied, including copies of any relevant press releases and the like. This information will be assessed to determine whether it fulfils the requirements of this clause.

Public assessment reports (European or UK), summaries of product characteristics and package leaflets may be provided to members of the public on request.

Companies may provide members of the health professions with leaflets concerning a medicine with a view to their provision to patients to whom the medicine has already been prescribed, provided that such a leaflet is factual and non-promotional in nature.

A company may conduct a disease awareness or public health campaign provided that the purpose is to encourage members of the public to seek treatment for their symptoms while in no way promoting the use of a specific medicine. The use of brand or non-proprietary names and/or restricting the range of treatments described in the campaign might be likely to lead to the use of a specific medicine. Particular care must be taken where the company's product, even though not named, is the only medicine relevant to the disease or symptoms in question.

Attention is drawn to the Disease Awareness Campaigns Guidelines produced by the Medicines and Healthcare products Regulatory Agency.

The requirements of Clause 7 relating to information (Clauses 7.2, 7.4, 7.5, 7.8, 7.9, 7.10 and 7.11) also apply to information to the public.

Meetings organised for or attended by members of the public, journalists and patient organisations must comply with Clause 19.

Items for patients or for use by patients are covered in the supplementary information to Clause 18.2.

Clause 20.2 Financial Information

Information made available in order to inform shareholders, the Stock Exchange and the like by way of annual reports and announcements etc. may relate to both existing medicines and those not yet marketed. Such information must be factual and presented in a balanced way. Business press releases should identify the business importance of the information.

Clause 20.2 Information to Current or Prospective Employees

Information about pharmaceutical companies provided to current or prospective employees may relate to both existing medicines and those not yet marketed. Such information must be factual and presented in a balanced way.

Clause 20.2 Approval of Information

Information on medicines made available under this clause other than responses from medical information departments or similar to unsolicited enquiries from the public must be certified in advance as required by Clause 14.3.

Clause 20.2 Health Technology Assessments

Companies may supply information to relevant patient organisations, the public or patients in relation to forthcoming health technology assessments by public national organisations such as NICE, AWMSG or SMG, provided the information is accurate, not misleading, not promotional in nature and otherwise complies with Clause 20.2.

Clause 20.3 Relationships with Patient Organisations

Pharmaceutical companies can interact with patient organisations or any user organisation such as disability organisations, carer or relative organisations and consumer organisations to support their work, including assistance in the provision of appropriate information to the public, patients and carers. Any involvement a pharmaceutical company has with a patient organisation must be declared and transparent. Companies must make public by means of information on their websites or in their annual report a list of all patient organisations to which they provide financial support. This might include sponsoring materials and meetings. Matters to be borne in mind include arrangements for meetings (Clause 19), the need to declare sponsorship (Clause 9.10) and the prohibition on advertising prescription only medicines to the general public (Clause 20.1).

Companies working with patient organisations must have in place a written agreement setting out exactly what has been agreed, including funding, in relation to every significant activity or ongoing relationship. The written agreement should set out the activities agreed and the level of funding and refer to the approval process for each party. Attention is

drawn to the certification requirements set out in Clause 14.3.

There are other codes and guidelines which cover patient groups, including the Long Term Medical Conditions Alliance guidelines and Charity Commission requirements etc.

Pharmaceutical companies should take into account the purpose of materials and/or activities. The purpose of information supplied to a patient organisation must be made clear. For example, there is a difference between providing information to be supplied to the members of a patient organisation and providing background information to enable a patient organisation to respond to a health technology assessment or similar.

Clause 20.4 Requests for Information or Advice on Personal Medical Matters

This clause prohibits the provision of advice on personal medical matters to individual members of the public requesting it. The intention behind this prohibition is to ensure that companies do not intervene in the patient/doctor or patient/prescriber relationship by offering advice or information which properly should be in the domain of the doctor or other prescriber.

Pharmaceutical companies can provide information appropriate to support the use of medicines and enhance patient welfare. Emergency advice, for example action needed in the event of an overdose, can be provided. Other information may also be given, including information on medicines prescribed for the enquirer, provided that it complies with the requirements of Clauses 20.1 and 20.2 and does not impinge on the principle behind this clause. For example, answering requests from members of the public as to whether a particular medicine contains sucrose or some other inactive ingredient, or whether there would be problems associated with drinking alcohol whilst taking the medicine or whether the medicine should be taken before or after a meal, is acceptable. Particular care needs to be taken with regard to enquiries relating to side-effects, the indications for a medicine and suchlike.

All requests from members of the public must be handled with great care and a company should refer the enquirer to other sources where appropriate. These might include health professionals, NHS Direct and patient organisations, etc.

A request from a patient for information may in some instances best be handled by passing the information to the patient's doctor or other prescriber for discussion with them rather than providing the information direct to the patient concerned. This should not be done without the patient's consent.

Clause 21 The Internet

21.1 Access to promotional material directed to a UK audience provided on the Internet in relation to prescription only medicines should generally be limited to health professionals and appropriate administrative staff.

21.2 Information or promotional material about medicines covered by Clause 21.1 above which is placed on the Internet outside the UK will be regarded as coming within the scope of the Code if it was placed there by a UK company or an affiliate of a UK company or at the instigation or with the authority of such a company and it makes specific reference to the availability or use of the medicine in the UK.

21.3 Information about medicines covered by Clauses 21.1 and 21.2 above which is provided on the Internet and which can be accessed by members of the public must comply with Clause 20.2 of the Code.

21.4 Notwithstanding the provisions of Clauses 21.1 and 21.3 above, a medicine covered by Clause 21.1 may be advertised in a relevant independently produced electronic journal intended for health professionals or appropriate administrative staff which can be accessed by members of the public.

21.5 Public assessment reports (European or UK), summaries of product characteristics, package leaflets and reference material for prescription only medicines may be included on the Internet and be accessible by members of the public provided that they are not presented in such a way as to be promotional in nature.

21.6 It should be made clear when a user is leaving any of the company's sites, or sites sponsored by the company, or is being directed to a site which is not that of the company.

Clause 22 Compliance with Undertakings

When an undertaking has been given in relation to a ruling under the Code, the company concerned must ensure that it complies with that undertaking.

Clause 21.1 Access

Promotional material should ideally be access restricted. If, however, access restriction is not applied, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This is to avoid the public needing to access material for health professionals unless they choose to. The MHRA Blue Guide states that the public should not be encouraged to access material which is not intended for them.

Clause 21.4 Advertisements in Electronic Journals

It should be noted that the MHRA Blue Guide states that each page of an advertisement for a prescription only medicine should be clearly labelled as intended for health professionals.

Clause 21.5 MHRA Guidance

The MHRA Blue Guide states that the public should not need to access non-UK websites or non-UK parts of websites to obtain basic information about a company's products, such as patient information leaflets, summaries of product characteristics, public assessment reports and other non promotional material. It is good practice for each page of a company website to include a statement identifying the intended audience.

Clause 21.5 Information on Clinical Trials

Information on clinical trials as agreed in the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases 2005 may be available at a UK or a non UK website.

Clause 21.6 Sites Linked via Company Sites

Sites linked via company sites are not necessarily covered by the Code.

PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY

Constitution and Procedure

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PREScription MEDICINES CODE OF PRACTICE AUTHORITY

CONSTITUTION AND PROCEDURE

Operative on 1 January 2006 except for paragraphs 5, 6, 7, 8, 10, 11, 12, 13, 16.3 and 21 which are operative in respect of complaints received on and after 1 January 2006.

INTRODUCTION

The Code of Practice for the Pharmaceutical Industry is administered by the Prescription Medicines Code of Practice Authority. The Authority is responsible for the provision of advice, guidance and training on the Code of Practice as well as for the complaints procedure. It is also responsible for arranging for conciliation between companies when requested to do so and for scrutinising advertising and meetings on a regular basis. Complaints made under the Code about promotional material or the promotional activities of companies are considered by the Code of Practice Panel and, where required, by the Code of Practice Appeal Board. Reports on cases are published by the Authority and are available on request and on the Authority's website www.pmcpa.org.uk.

The names of individuals complaining from outside the pharmaceutical industry are kept confidential. In exceptional cases it may be necessary for a company to know the identity of the complainant so that the matter can be properly investigated. Even in these instances, the name of the complainant is only disclosed with the complainant's permission.

Complaints about the promotion of medicines should be submitted to the Director of the Prescription Medicines Code of Practice Authority, 12 Whitehall, London SW1A 2DY, telephone 020-7930 9677, facsimile 020-7930 4554, email complaints@pmcpa.org.uk.

STRUCTURE AND RESPONSIBILITIES

1 Prescription Medicines Code of Practice Authority

1.1 The Prescription Medicines Code of Practice Authority is responsible for the administration of the Code of Practice for the Pharmaceutical Industry including the provision of advice, guidance and training on the Code. It is also responsible for arranging for conciliation between companies when requested to do so and for scrutinising advertising and meetings on a regular basis.

1.2 The Authority also administers the complaints procedure by which complaints made under the Code are considered by the Code of Practice Panel and, where required, by the Code of Practice Appeal Board.

1.3 The Authority is appointed by and reports to the Board of Management of The Association of the British Pharmaceutical Industry (ABPI) and consists of the Director, Secretary and Deputy Secretary.

The Director reports to the Appeal Board for guidance on the interpretation of the Code and the operation of the complaints procedure and to the President of the ABPI for administrative purposes.

In the absence of the Director, the Secretary is authorised to act on his behalf.

1.4 The Director has the authority to request copies of any relevant material from a pharmaceutical company, including copies of the certificates authorizing any such material and copies of relevant briefing material for representatives.

1.5 The Authority may consult the Appeal Board upon any matter concerning the Code or its administration.

2 Code of Practice Panel – Constitution and Procedure

2.1 The Code of Practice Panel consists of the members of the Prescription Medicines Code of Practice Authority and meets as business requires to consider complaints made under the Code.

2.2 Two members of the Authority form a quorum for a meeting of the Panel. Decisions are made by majority voting. The Director or, in his absence, the Secretary, acts as Chairman of the Panel and has both an original and a casting vote.

2.3 The Director may obtain expert assistance in any field. Expert advisers who are consulted may be invited to attend a meeting of the Panel but have no voting rights.

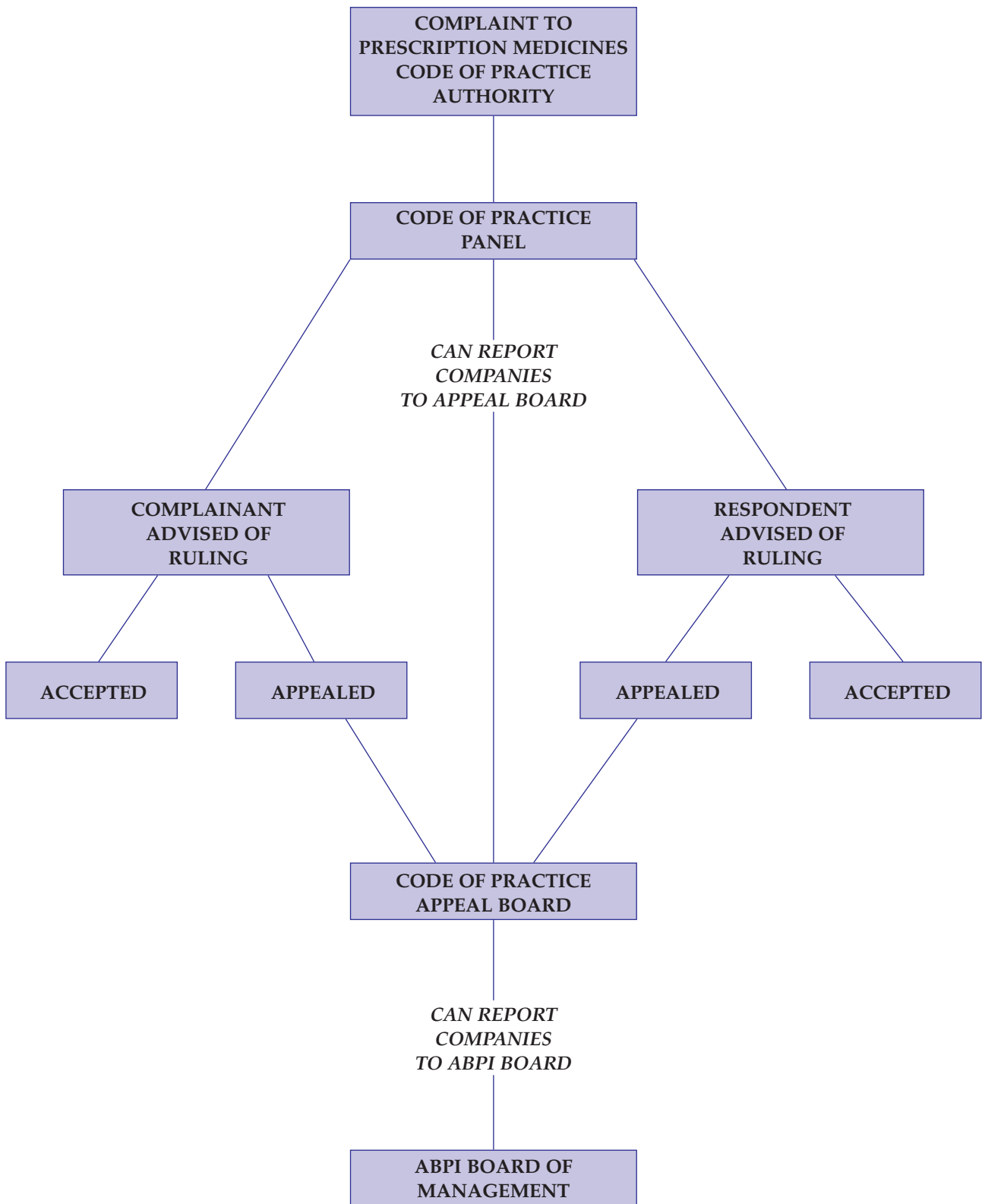
3 Code of Practice Appeal Board – Constitution

3.1 The Code of Practice Appeal Board and its Chairman are appointed by the Board of Management of the ABPI. The appointment of independent members to the Appeal Board is made following consultation with the Medicines and Healthcare products Regulatory Agency.

Vacancies for independent members other than the Chairman are advertised in appropriate journals and/or the national press.

3.2 The Appeal Board comprises:

- an independent, legally qualified Chairman
- three independent registered medical practitioners appointed following consultation with the British Medical Association, one with recent experience as a general practitioner and one with recent experience as a hospital consultant



- one independent practising registered pharmacist appointed following consultation with the Royal Pharmaceutical Society of Great Britain
- one independent registered nurse prescriber appointed following consultation with the Royal College of Nursing
- one independent member representative of the interests of patients
- one member from an independent body involved in providing information on medicines
- one independent member who is not a health professional
- four registered medical practitioners who are medical directors or senior executives of pharmaceutical companies
- eight directors or senior executives of pharmaceutical companies.

One of the members from pharmaceutical companies may be retired, provided that the initial appointment is made within one year of the date of retirement.

- 3.3** The Chairman of the Appeal Board is appointed for a term of five years which may be renewed.

Members of the Appeal Board are each appointed for a term of three years. Members may be reappointed but may serve for no more than two consecutive terms. In exceptional circumstances the Chairman may nominate a member who has served two terms for reappointment for a third term. A member of the Appeal Board who has served two or, following the Chairman's nomination, three consecutive terms of service is eligible for reappointment after a minimum interval of one year.

A member of the Appeal Board appointed prior to 1 January 2006 is eligible to serve for two or, following the Chairman's nomination, three further consecutive terms following completion of their current term and is eligible for reappointment after a minimum interval of one year.

- 3.4** The Director is responsible for providing appropriate administrative support to the Appeal Board.

The Director, Secretary and Deputy Secretary of the Authority may be present at a meeting of the Appeal Board during the consideration of an appeal or a report under Paragraph 11 below only at the invitation of the Chairman and with the agreement of the party or parties involved in the appeal or report in question.

4 Code of Practice Appeal Board – Procedure

- 4.1** The Code of Practice Appeal Board meets as business requires to consider appeals under the Code and any other matter which relates to the Code. The Appeal Board receives reports on all complaints which have been submitted under the Code and details of the action taken on them.

- 4.2** The Chairman and seven members of the Appeal Board constitute a quorum. Two of those present must be independent members, at least one of whom must be a registered medical practitioner, and there must also be present two members from pharmaceutical companies, at least one of whom must be a registered medical practitioner.

In the event that a quorum cannot be attained for the consideration of a case because of the number of members barred under Paragraph 4.4 below, or for any other reason, the Chairman may co-opt appropriate persons who are former members of the Appeal Board, or who are on a list of persons approved for co-option to the Appeal Board, so as to enable a quorum to be achieved. The list of persons approved for co-option is drawn up following procedures similar to those for appointing members of the Appeal Board.

- 4.3** Decisions are made by majority voting. The Chairman has both an original and a casting vote.

- 4.4** If a member of the Appeal Board is concerned in a case either as complainant or respondent, that member does not receive copies of the papers circulated in connection with the case and is required to withdraw from the Appeal Board during its consideration.

Members of the Appeal Board are also required to declare any other interest in a case prior to its consideration. The Chairman determines whether it is appropriate for that member to remain for the consideration of the case.

- 4.5** The Chairman may obtain expert assistance in any field. Expert advisers may be invited to attend a meeting of the Appeal Board but have no voting rights.

- 4.6** When an appeal is considered by the Appeal Board, both the complainant and the respondent company are entitled to appear or be represented.

The first presentation in relation to a ruling which is appealed is made by the appellant.

A company may not be represented before the Appeal Board by a representative who is also a member of the Appeal Board except with the consent of the Chairman. Such consent may be given only if the member of the Appeal Board can satisfy the Chairman that no other person within his company can properly represent it in the case in question.

- 4.7** Where an appeal is brought which is concerned with an issue of fact between a complainant and the company concerned which cannot be properly resolved without the oral evidence of the persons directly involved, the Chairman may invite such persons to attend and give evidence.

COMPLAINTS PROCEDURE

5 Action on Complaints

- 5.1 When the Director receives information from which it appears that a company (being either a member of the ABPI or a company which, although not a member, has agreed to comply with the Code and accept the jurisdiction of the Authority) may have contravened the Code, the managing director or chief executive or equivalent of the company concerned is requested to comment on the matters of complaint.

If a complaint is received about a company other than one of those referred to above, it is invited to agree to comply with the Code and accept the jurisdiction of the Authority (unless it has previously declined to do so). In the absence of such agreement, the complaint is not proceeded with and the complainant is advised to refer the matter to the Medicine and Healthcare products Regulatory Agency.

If a complaint concerns a matter closely similar to one which has been the subject of a previous adjudication, it may be allowed to proceed at the discretion of the Director if new evidence is adduced by the complainant or if the passage of time or a change in circumstances raises doubts as to whether the same decision would be made in respect of the current complaint. The Director should normally allow a complaint to proceed if it covers matters similar to those in a decision of the Code of Practice Panel which was not the subject of appeal to the Code of Practice Appeal Board.

If a complainant does not accept a decision of the Director that a complaint should not be proceeded with because a similar complaint has been adjudicated upon previously and nothing has changed in the meantime, then the matter is referred to the Chairman of the Appeal Board for his decision which is final.

If, in the view of the Director, a complaint does not show that there may have been a breach of the Code, the complainant shall be so advised. If the complainant does not accept that view, the matter is referred to the Chairman of the Appeal Board for his decision which is final.

- 5.2 When the complaint is from a pharmaceutical company, the complaint must be signed or authorized in writing by the company's managing director or chief executive or equivalent and must state those clauses of the Code which are alleged to have been breached.

A complaint from a pharmaceutical company will be accepted only if the Director is satisfied that the company concerned has previously informed the company alleged to have breached the Code that it proposed to make a formal complaint and offered inter-company dialogue at a senior level in an attempt to resolve the matter,

but that this offer was refused or dialogue proved unsuccessful. A formal statement detailing the actions taken must be provided.

Attention is drawn to the availability of conciliation prior to making a complaint as referred to in Paragraph 19.2 below. Information about conciliation is available from the Authority.

- 5.3 Upon receipt of a complaint, the company concerned has ten working days in which to submit its comments in writing.
- 5.4 When a company advises the Authority that it may have breached the Code, the Director shall treat the matter as a complaint if it relates to a potentially serious breach of the Code or if the company fails to take appropriate action to address the matter. The company's comments are invited and the Director must then determine within two working days whether a *prima facie* case has been established. If a *prima facie* case is established the procedures under Paragraph 6.2 below onwards shall be followed.

6 Establishment of *Prima Facie* Case and Consideration by the Code of Practice Panel

- 6.1 Upon receipt of the comments from the respondent company, the Director must determine within two working days whether there is a *prima facie* case to answer under the Code. If, in the view of the Director, no *prima facie* case has been established the complainant and the respondent company are so advised. If the complainant does not accept that view, the matter is referred to the Chairman of the Code of Practice Appeal Board for his decision which is final.

If the complainant submits further evidence which, in the view of the Director, shows that there may have been a breach of the Code, then the respondent company shall be invited to comment on that further evidence. Upon receipt of the further comments from the respondent company, the Director must determine within two working days whether a *prima facie* case has been established. If, in the view of the Director, no *prima facie* case has been established the complainant and the respondent company are so advised. If the complainant does not accept that view, the matter is referred to the Chairman of the Appeal Board for his decision which is final.

- 6.2 Once it has been determined that a *prima facie* case exists, the case is referred to the Code of Practice Panel to determine whether or not there has been a breach of the Code.

7 Code of Practice Panel: Rulings

- 7.1 Where the Code of Practice Panel rules that there is a breach of the Code, the complainant and the respondent company are so advised in writing and are given the reasons for the decision.

If the promotional material or activity at issue is considered by the Panel to be likely to prejudice public health and/or patient safety, and/or it represents a serious breach of the Code, the Panel must decide whether, if there is subsequently an appeal by the respondent company, it would be required to suspend the use of the material or activity pending the final outcome of the case. If suspension would be required, the company must be so notified when it is advised of the Panel's ruling of a breach of the Code.

The respondent company has five working days to provide a written undertaking that the promotional activity or use of the material in question and any similar material (if not already discontinued or no longer in use) will cease forthwith and that all possible steps will be taken to avoid a similar breach of the Code in the future. This undertaking must be signed by the managing director or chief executive or equivalent of the company or with his authority and must be accompanied by details of the actions taken by the company to implement the undertaking, including the date on which the promotional material was finally used or appeared and/or the last date on which the promotional activity took place.

In exceptional circumstances, an extension in the time allowed in which to respond may be granted at the discretion of the Director in accordance with Paragraph 14 below.

The company must also pay within twenty working days an administrative charge based on the number of matters ruled in breach of the Code.

- 7.2 Where the Panel rules that there is no breach of the Code, the complainant and the respondent company are so advised in writing and are given the reasons for the decision. Where the complaint is from a pharmaceutical company, the complainant must pay within twenty working days an administrative charge based on the number of matters alleged and ruled not to be in breach of the Code.

When advised of the outcome, the complainant will be sent a copy of the comments and enclosures submitted by the respondent company in relation to the complaint. If the respondent company objects to this because it regards part of the material as being confidential, and the matter cannot be settled by the Director, then it will be referred to the Chairman of the Code of Practice Appeal Board for his decision which is final.

- 7.3 The complainant or the respondent company may appeal against a ruling of the Panel to the Appeal Board. Appeals must be accompanied by reasons as to why the Panel's ruling is not accepted. These reasons will be circulated to the Appeal Board.

An appeal by the complainant must be lodged within ten working days of notification of the ruling of the Panel.

Where the respondent company appeals, it must give notice of appeal within five working days of notification of the ruling of the Panel and must lodge the appeal within ten working days of notification of the ruling of the Panel.

If the Panel has so required in accordance with Paragraph 7.1 above, where the respondent company gives notice of appeal it must, within five working days of notification of the Panel's ruling, suspend the use of the promotional material or activity at issue, pending the final outcome of the case, and must notify the Authority that such action has been taken.

If the respondent company accepts one or more of the Panel's rulings of breaches of the Code, but appeals one or more other such rulings, then within five working days of notification of the Panel's rulings it must provide the undertaking required by Paragraph 7.1 above in respect of the ruling or rulings which it is not appealing.

In exceptional circumstances, an extension in the time allowed in which to respond may be granted at the discretion of the Director in accordance with Paragraph 14 below.

- 7.4 Where an appeal is lodged by the complainant, the respondent company has five working days to comment on the reasons given by the complainant for the appeal and these comments will be circulated to the Appeal Board.

The complainant has five working days to comment on the respondent company's comments upon the reasons given by the complainant for the appeal and these comments will be circulated to the respondent company and the Appeal Board.

In the event that the respondent company objects to certain of its comments being made available to the complainant on the grounds of confidentiality, and the matter cannot be settled by the Director, then it will be referred to the Chairman of the Appeal Board who will decide whether those particular comments can be included in the evidence which goes before the Appeal Board. The Chairman's decision is final.

- 7.5 Where an appeal is lodged by the respondent company, the complainant has five working days to comment on the reasons given by the respondent company for the appeal and these comments will be circulated to the respondent company and the Appeal Board.

In the event that the respondent company objects to certain details of its appeal being made available to the complainant on the grounds of confidentiality, and the matter cannot be settled by the Director, then it will be referred to the Chairman of the Appeal Board who will decide whether those particular details can be included in the evidence which goes before the Appeal Board. The Chairman's decision is final.

Where an appeal is lodged by the respondent company, the complainant is sent a copy of the initial comments and enclosures submitted by the respondent company in relation to the complaint. If the respondent company objects to this because it regards part of the material as being confidential, and the matter cannot be settled by the Director, then it will be referred to the Chairman of the Appeal Board for his decision which is final.

8 Code of Practice Panel: Reports to the Code of Practice Appeal Board

8.1 Failure to comply with the procedures set out in Paragraphs 5, 6 and 7 above shall be reported to the Code of Practice Appeal Board.

8.2 The Code of Practice Panel may also report to the Appeal Board any company whose conduct in relation to the Code, or in relation to a particular case before it, or because it repeatedly breaches the Code such that it raises concerns about the company's procedures, warrants consideration by the Appeal Board. Such a report to the Appeal Board may be made notwithstanding the fact that a company has provided an undertaking requested by the Panel.

9 Action on Complaints about Safety from the Medicines and Healthcare products Regulatory Agency

9.1 In the event of the Medicines and Healthcare products Regulatory Agency making a complaint which relates to the safety or proper use of a medicine, and requesting that an advertisement be withdrawn, the respondent company has five working days to respond with its comments.

9.2 If the Code of Practice Panel upholds the complaint, the company is required to suspend the advertisement or practice forthwith pending the final outcome of the case.

10 Code of Practice Appeal Board: Rulings

10.1 Where the Code of Practice Appeal Board rules that there is no breach of the Code, the complainant and the respondent company are so advised in writing and are given the reasons for the decision.

Where a complainant pharmaceutical company appeals and the Appeal Board upholds the ruling that there is no breach of the Code, the complainant pharmaceutical company must pay within twenty working days an administrative charge based on the number of matters taken to appeal on which no breach is ruled.

Where a respondent company appeals and the Appeal Board rules that there is no breach of the Code, the complainant pharmaceutical company

must pay within twenty working days an administrative charge based on the number of matters taken to appeal on which no breach is ruled.

10.2 Where the Appeal Board rules that there is a breach of the Code, the respondent company is so advised in writing and is given the reasons for the decision. The respondent company then has five working days to provide a written undertaking providing the information specified in Paragraph 7.1 above.

The company must also pay within twenty working days an administrative charge based on the number of matters ruled in breach of the Code.

10.3 Where the Appeal Board rules that there is a breach of the Code, the company may be required by the Appeal Board to take steps to recover items given in connection with the promotion of a medicine or non promotional items provided to members of the public and the like. Details of the action taken must be provided in writing to the Appeal Board.

10.4 Where the Appeal Board rules that there is a breach of the Code, the Appeal Board may require an audit of the company's procedures in relation to the Code to be carried out by the Prescription Medicines Code of Practice Authority and, following that audit, decide whether to impose requirements on the company concerned to improve its procedures in relation to the Code. These could include a further audit and/or a requirement that promotional material be submitted to the Authority for pre-vetting for a specified period. The Authority must arrange for material submitted for pre-vetting to be examined for compliance with the Code but the Authority cannot approve such material.

The Appeal Board may also require an audit if a company repeatedly breaches the Code.

10.5 Where the Appeal Board rules that there is a breach of the Code, the Appeal Board may reprimand the company and publish details of that reprimand.

10.6 Where the Appeal Board rules that there is a breach of the Code, the Appeal Board may require the company to issue a corrective statement. Details of the proposed content and mode and timing of dissemination of the corrective statement must be provided to the Appeal Board for approval prior to use.

11 Reports to the Code of Practice Appeal Board

11.1 Where the Panel reports a company to the Code of Practice Appeal Board under the provisions of Paragraphs 8.1 and 8.2 above, or where the Panel reports the failure of a company to comply with the procedures set out in Paragraph 9 above, or where the Authority reports the failure of a company to comply with the procedures set out in Paragraph 10 above, the procedures set out below shall apply. These procedures also apply if the Appeal Board, having received a report on a case completed at the Panel level, in accordance with Paragraph 4.1 above, considers that additional sanctions may be appropriate.

11.2 The company concerned is provided with a copy of the report prior to its consideration and is entitled to have a representative or representatives appear before the Appeal Board to state the company's case.

A company may not be represented before the Appeal Board by a representative who is also a member of the Appeal Board except with the consent of the Chairman. Such consent may be given only if the member of the Appeal Board can satisfy the Chairman that no other person within his company can properly represent it in the matter in question.

11.3 The Appeal Board may decide:

- to reprimand the company and publish details of that reprimand
- to require an audit of the company's procedures in relation to the Code to be carried out by the Prescription Medicines Code of Practice Authority and, following that audit, decide whether to impose requirements on the company concerned to improve its procedures in relation to the Code; these could include a further audit and/or a requirement that promotional material be submitted to the Authority for pre-vetting for a specified period; the Authority must arrange for material submitted for pre-vetting to be examined for compliance with the Code but the Authority cannot approve such material
- to require the company to issue a corrective statement; details of the proposed content and mode and timing of dissemination of the corrective statement must be provided to the Appeal Board for approval prior to use
- to take steps to recover items given in connection with the promotion of a medicine; details of the action taken must be provided in writing to the Appeal Board.

11.4 Where a company not in membership of the ABPI fails to comply with the procedures set out in Paragraphs 5, 6, 7, 9 or 10 above and indicates that it no longer wishes to accept the jurisdiction of the Authority, the Appeal Board may decide that the

company should be removed from the list of non member companies which have agreed to abide by the Code and the Medicines and Healthcare products Regulatory Agency advised that responsibility for that company under the Code can no longer continue to be accepted.

The Board of Management of the ABPI must be advised that such action has been taken.

12 Code of Practice Appeal Board: Reports to the ABPI Board of Management

12.1 Where the Code of Practice Appeal Board considers that the conduct of a company in relation to the Code or a particular case before it warrants such action, it may report the company to the Board of Management of the ABPI for it to consider whether further sanctions should be applied against that company. Such a report may be made notwithstanding the fact that the company has provided an undertaking requested by either the Code of Practice Panel or the Appeal Board.

12.2 Where such a report is made to the Board of Management, the Board of Management may decide:

- to reprimand the company and publish details of that reprimand
- to require an audit of the company's procedures in relation to the Code to be carried out by the Prescription Medicines Code of Practice Authority and, following that audit, decide whether to impose requirements on the company concerned to improve its procedures in relation to the Code; these could include a further audit and/or a requirement that promotional material be submitted to the Authority for pre-vetting for a specified period; the Authority must arrange for material submitted for pre-vetting to be examined for compliance with the Code but the Authority cannot approve such material
- to require the company to issue a corrective statement; details of the proposed content and mode and timing of dissemination of the corrective statement must be provided to the Appeal Board for approval prior to use
- to suspend or expel the company from the ABPI or
- in the case of companies not in membership of the ABPI, to remove the company from the list of non member companies which have agreed to abide by the Code and to advise the Medicines and Healthcare products Regulatory Agency that responsibility for that company under the Code can no longer continue to be accepted.

12.3 If a member of the Board of Management is concerned in a case which has led to the report, as either complainant or respondent, that member does not receive a copy of the report and is

required to withdraw from the Board of Management during its consideration.

Members of the Board of Management are also required to declare any other interest in a report prior to its consideration. The President (or Chairman in the absence of the President) determines whether it is appropriate for that member to remain for the consideration of the report.

- 12.4 Where a report is made to the Board of Management under Paragraph 12.1 above, the company concerned is provided with a copy of the report prior to its consideration and is entitled to have a representative or representatives appear before the Board of Management to state the company's case.

13 Case Reports

- 13.1 At the conclusion of any case under the Code, the complainant is advised of the outcome and a report is published summarising the details of the case.

- 13.2 The respondent company and the medicine concerned are named in the report.

In a case where the complaint was initiated by a company or by an organisation or official body, that company or organisation or official body is named in the report. The information given must not, however, be such as to identify any individual person.

Where expert assistance has been obtained by either the Code of Practice Panel or the Code of Practice Appeal Board, the report will include the name and qualifications of the expert concerned.

Where a company has been required to issue a corrective statement, the report will reproduce its text and provide details of how the corrective statement was disseminated.

- 13.3 A copy of the report on a case is made available to both the complainant and the respondent company prior to publication. Any amendments to the report suggested by these parties are considered by the Director, consulting with the other party where appropriate. If either party does not accept the Director's decision as to whether or not a report should be amended, the matter is referred to the Chairman of the Appeal Board for his decision which is final.

- 13.4 Copies of all case reports are submitted to the Appeal Board prior to publication. Copies of the reports are sent to the ABPI Board of Management for information following publication.

- 13.5 Full case reports in printed form are published by the Authority on a quarterly basis.

Copies of the reports are sent to the Medicines and Healthcare products Regulatory Agency, the Office of Fair Trading, the British Medical Association, the Royal Pharmaceutical Society of Great Britain, the Royal College of Nursing and the Editors of the BMJ, The Pharmaceutical Journal and the Nursing Standard. Copies are also available to anyone on request.

- 13.6 In addition to the printed reports, full case reports appear on the Authority's website. The website also carries brief details of all complaints in which a *prima facie* case has been established and which are currently under consideration but not yet resolved and the texts and modes of dissemination of any corrective statements that companies have been required to issue during the previous twelve months.

Access to the Authority's website is unrestricted.

- 13.7 Following publication of the relevant case reports, the Authority advertises in the medical and pharmaceutical press brief details of cases in which companies were ruled in breach of Clause 2 of the Code, were required to issue a corrective statement or were the subject of a public reprimand. Such advertisements also appear on the Authority's website.

GENERAL PROVISIONS

14 Time Periods for Responding to Matters under the Code

The number of working days within which companies or complainants must respond to enquiries etc, from the Prescription Medicines Code of Practice Authority, as referred to in the above procedures, are counted from the date of receipt of the notification in question.

An extension in time to respond to such notifications may be granted at the discretion of the Director.

15 Withdrawal of Complaints and Notices of Appeal

- 15.1 A complaint may be withdrawn by a complainant with the consent of the respondent company up until such time as the respondent company's comments on the complaint have been received by the Prescription Medicines Code of Practice Authority, but not thereafter.

- 15.2 Notice of appeal may be withdrawn by a complainant with the consent of the respondent company up until such time as the respondent company's comments on the reasons for the appeal have been received by the Authority, but not thereafter.

- 15.3 Notice of appeal may be withdrawn by a respondent company at any time but if notice is given after the papers relating to its appeal have been circulated to the Code of Practice Appeal Board, then the higher administrative charge will be payable.

16 Code of Practice Levy and Charges

- 16.1 An annual Code of Practice levy is paid by members of the ABPI. The levy together with the administrative charges referred to in Paragraphs 7 and 10 above and the charges for audits carried out in accordance with Paragraphs 10.4, 11.3 and 12.2 above are determined by the Board of Management of the ABPI subject to approval at a General Meeting of the ABPI by a simple majority of those present and voting.

- 16.2 Administrative charges are payable only by pharmaceutical companies and companies are liable for such charges whether they are members of the ABPI or not.

There are two levels of administrative charge.

The lower level is payable by a company which accepts either a ruling of the Code of Practice Panel that it was in breach of the Code or a rejection by the Panel of its allegation against another company. The lower level is also payable by a complainant company if a ruling of the Panel that there was a breach of the Code is subsequently overturned by the Code of Practice Appeal Board and by a respondent company if a ruling of the Panel that there was no breach of the Code is subsequently overturned by the Appeal Board.

The higher level is paid by a company which unsuccessfully appeals a decision of the Panel.

- 16.3 Where two or more companies are ruled in breach of the Code in relation to a matter involving co-promotion, each company shall be separately liable to pay any administrative charge which is payable.

- 16.4 The number of administrative charges which apply in a case is determined by the Director. If a company does not agree with the Director's decision, the matter is referred to the Chairman of the Appeal Board for his decision which is final.

- 16.5 Failure to pay any of the charges provided for by this paragraph must be reported by the Director to the Appeal Board or the Board of Management of the ABPI as appropriate.

17 Possible Breaches identified by the Code of Practice Panel or Code of Practice Appeal Board

Where the Code of Practice Panel or Code of Practice Appeal Board identifies a possible breach of the Code which has not been addressed by the complainant in a case, the Director shall

treat the matter as a complaint. The company's comments are invited and the Director must then determine within two working days whether a *prima facie* case has been established. If a *prima facie* case is established the procedures under Paragraph 6.2 above onwards shall be followed.

18 Scrutiny

- 18.1 Samples of advertisements, detail aids, leave-pieces, other promotional items and meetings are scrutinised by the Prescription Medicines Code of Practice Authority on a continuing basis in relation to the requirements of the Code.

To facilitate such scrutiny, the Director has the authority to request relevant material from pharmaceutical companies, including copies of the certificates authorizing such material, and companies must respond to such requests within ten working days.

- 18.2 Where a *prima facie* breach of the Code is identified under this procedure, the company concerned is requested to comment in writing within ten working days of receipt of the notification.

- 18.3 If the company accepts that there is a breach of the Code, the company is requested to provide an undertaking providing the information specified in Paragraph 7.1 above. No administrative charge shall be payable in these circumstances and there shall be no case report on the matter in question.

- 18.4 If the company does not accept that there is a breach of the Code and, having considered the company's comments, the Director decides that there is no *prima facie* case to answer under the Code, then the procedure is brought to a close. There shall be no case report on the matter in question.

- 18.5 If the company does not accept that there is a breach of the Code but, having considered the company's comments, the Director considers that a *prima facie* case has been established, the procedures under Paragraph 6.2 above onwards shall be followed.

19 Provision of Advice and Assistance with Conciliation

- 19.1 The Prescription Medicines Code of Practice Authority is willing and able to provide informal guidance and advice in relation to the requirements of the Code and, where appropriate, may seek the views of the Code of Practice Appeal Board.

- 19.2 Companies wishing to seek the assistance of a conciliator with the view to reaching agreement on inter-company differences about promotion

may contact the Director for advice and assistance.

20 Amendments to the Code of Practice and Constitution and Procedure

20.1 The Code of Practice for the Pharmaceutical Industry and this Constitution and Procedure may be amended by a simple majority of those present and voting at a General Meeting of the ABPI.

20.2 The views of the Prescription Medicines Code of Practice Authority and the Code of Practice Appeal Board must be sought on any proposal to amend the Code or this Constitution and Procedure. The views of the Medicines and Healthcare products Regulatory Agency, the British Medical Association, the Royal Pharmaceutical Society of Great Britain and the Royal College of Nursing must also be invited.

20.3 The Prescription Medicines Code of Practice Authority and the Code of Practice Appeal Board may, in the light of their experience, make recommendations for amendment of the Code and this Constitution and Procedure.

21 Annual Report

An annual report of the Prescription Medicines Code of Practice Authority is published each year with the approval of the Code of Practice Appeal Board. This report includes details of the work of the Authority, the Code of Practice Panel and the Appeal Board during the year and provides a list of all companies ruled in breach of the Code during the year which specifically identifies those ruled to have breached Clause 2.

GUIDELINES ON COMPANY PROCEDURES RELATING TO THE CODE OF PRACTICE

Paragraphs 10.4, 11.3 and 12.2 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority variously authorize the Code of Practice Appeal Board and the Board of Management of The Association of the British Pharmaceutical Industry to require an audit of a company's procedures in relation to the Code of Practice for the Pharmaceutical Industry to be carried out by the Prescription Medicines Code of Practice Authority.

Set out below are guidelines on company procedures which are regarded as representing good practice in this regard. They are minimum requirements and will need to be adapted to fit in with the arrangements at any particular company.

1) Certification of Promotional Material

Procedures must ensure that:

- promotional material is not issued until its final form has been certified in accordance with Clause 14 of the Code
- the names of signatories are notified in advance to the Product Information and Advertising Unit of the Post Licensing Division of the Medicines and Healthcare products Regulatory Agency and to the Prescription Medicines Code of Practice Authority (Clause 14.4)
- the form of certificate encompasses at least the requirements of Clause 14.5
- material still in use is recertified at intervals of no more than two years (Clause 14.5)
- the certificates, together with the material in the form certified and information as to whom it was addressed, the method of dissemination and the date of first dissemination are preserved for at least three years after final use (Clause 14.6).

Each certificate should bear a reference number with the same reference number appearing on the promotional material in question so that there can be no doubt as to what has been certified. A particular reference number should relate to only one item of promotional material.

Different sizes and different layouts of a piece of promotional material should be separately certified and each should have its own unique reference number.

2) Representatives' Briefing and Training Materials

The certification requirements of Clause 14 which are covered above apply also to briefing material prepared for representatives in accordance with Clause 15.9. Briefing material includes the training material used to instruct medical representatives about a medicine and the instructions given to them as to how the product should be promoted.

Procedures must ensure that no such material is used or issued prior to certification.

3) Representatives' Expenses

There should be a clearly laid down procedure for approval and payment of representatives' expenses and expenditure on meetings and hospitality and the like. A system should be in place for an audit on a systematic or random basis which will check the nature of the expenditure which has been incurred and assess whether that expenditure was in accordance with the requirements of the Code.

4) Representatives' Training

Procedures must ensure that:

- representatives (including contract representatives) are adequately trained in relation to every product which they are to promote (Clause 15.1)
- representatives are not employed as medical representatives or generic sales representatives unless they have passed the relevant examination as provided for in Clauses 16.3 and 16.4, or have been in such employment for less than two years (whether continuous or otherwise and irrespective of whether with one company or with more than one company)
- contract representatives are only employed or used if they comply with the requirements of Clauses 16.3 and 16.4 as regards examination status.

Representatives should be provided with written instructions on the application of the Code to their work even if they are also provided with an actual copy of it. Their instructions should cover such matters as the company's policies on meetings and hospitality, and the associated allowable expenditure, and the specific requirements for representatives in Clause 15. It should be made clear how reporting to the 'scientific service' of the company is to be carried out in relation to information about the medicines which they promote which comes to their notice, particularly reports of side-effects (Clause 15.6).

It should be made clear to representatives as to whether, and in what circumstances, they can themselves write letters (or prepare other written materials) which mention particular products and are thus almost certain to be considered promotional material.

Such items must be certified, either in advance by way of proforma letters or by certifying each individual letter or other item, and must bear prescribing information in accordance with Clause 4.1.

5) Training Generally

It should be ensured that all relevant personnel, including representatives and members of staff (including persons retained by way of contract with third parties) concerned in any way with the preparation or approval of promotional material or of information to be provided to members of the UK health professions or to appropriate administrative staff or of information to be provided to the public and recognised patient organisations, are fully conversant with the requirements of the Code and relevant legal requirements (Clause 16.1).

Appropriate arrangements should be in place for training on the requirements of the Code. These may be internal arrangements for appropriate staff members but key personnel should attend one of the seminars organised by the Prescription Medicines Code of Practice Authority.

It should also be ensured that all personnel (including persons retained by use of contract with third parties) are fully conversant with pharmacovigilance requirements relevant to their work and that this is fully documented (Clause 16.2).

Adequate arrangements should be in place to ensure that any information as to changes to the Code etc, including reports of decided cases, provided by the Authority are circulated to relevant personnel.

6) Provision of Medicines and Samples

Procedures should ensure that the requirements of Clause 17 are complied with.

Clause 17.9 requires companies to have adequate systems of control and accountability for samples and for all medicines handled by representatives. Similarly, there should be an adequate system to control the number of samples of a particular product given to a particular health professional in the course of a year (Clause 17.2).

7) Gifts, Inducements, Promotional Aids and the Provision of Medical and Educational Goods and Services

Procedures should ensure that Clause 18 is complied with and that promotional aids comply with Clauses 18.2 and 18.3.

Promotional aids must be certified in accordance with Clause 14.

The provision of medical and educational goods and services must be carried out in compliance with Clause 18.4 and must be certified in accordance with Clause 14.3.

8) Meetings and Hospitality

A company must have a written document that sets out its policies on meetings and hospitality and the associated allowable expenditure and

must ensure that all meetings that it plans are checked to see that they comply with Clause 19.

Meetings held outside the UK are not necessarily unacceptable but there have to be valid and cogent reasons for the use of a venue outside the UK (supplementary information to Clause 19.1).

Meetings which involve travel outside the UK must be formally certified in advance in accordance with Clause 14.2.

A company's procedures should cover its own meetings, those which it sponsors and the sponsorship of attendance at meetings.

9) Relations with the Public and the Media

Prescription only medicines must not be advertised to the public but information about them can be provided either directly or indirectly. The provision of information to the public about prescription only medicines must be in accordance with Clause 20.

Companies working with patient organisations must have in place a written agreement setting out what has been agreed, including funding (Clause 20.3).

10) The Internet

Access to promotional material on the Internet which is directed to a UK audience should ideally be limited to health professionals and appropriate administrative staff (Clause 21.1).

If, however, access is not restricted, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified.

11) Breaches of the Code

In the event of a company being found in breach of the Code, procedures should ensure that adequate steps are taken to ensure that relevant information about it is communicated internally to appropriate members of staff.

Procedures must be in place to ensure that promotional material found to be in breach of the Code is quickly and entirely withdrawn from use, not forgetting material stored electronically and/or in the hands of others, such as printers and agencies. They should include checks that claims etc found to be in breach do not also appear in other formats, such as exhibition stands, which might otherwise be overlooked.

Companies are advised to keep written records of the action taken to withdraw material.

12) Co-Promotion

Adequate provision should be made in co-promotion agreements and the like to ensure compli-

ance with the Code. Where companies jointly promote the same product and the promotional material bears both company names, each company must certify the promotional material involved as the companies concerned will be held jointly responsible for it under the Code (supplementary information to Clause 14.1).

13) Non-Promotional Items

Educational material for the public or patients (including material relating to working with patient organisations) relating to diseases or medicines, but which is not intended as promotion for those medicines, and non promotional information for patients or health professionals relating to the provision of medical and educational goods and services (including relevant internal instructions) must be certified in advance in accordance with Clause 14.3.

Other material issued by companies which relates to medicines but which is not intended as

promotion for those medicines, such as corporate advertising, press releases, market research material, financial information for shareholders and the Stock Exchange and responses to unsolicited enquiries from the public etc, should be examined to ensure that it does not contravene the Code or relevant statutory requirements.

Account should be taken of the fact that a non-promotional item can be used for a promotional purpose and therefore come within the scope of the Code.

14) Person Responsible for Compliance

Each company must have a senior employee who is responsible for ensuring that it meets the requirements of the Code (Clause 1.8).

Unless other formal arrangements have been made by a company, it will be assumed that the responsible person is the managing director or chief executive or equivalent.

LEGISLATION, OTHER CODES *and* GUIDELINES

LEGISLATION

- The Medicines Act 1968
Part VI Promotion of Sales of Medicinal Products
- The Medicines (Advertising) Regulations 1994
1994 No. 1932
- The Medicines (Advertising) Amendment
Regulations 1996
1996 No. 1552
- The Medicines (Monitoring of Advertising)
Regulations 1994
1994 No. 1933
- The Medicines (Advertising and Monitoring of
Advertising) Amendment Regulations 1999
1999 No. 267
- The Medicines (Monitoring of Advertising)
Amendment Regulations 1999
1999 No. 784
- The Medicines (Advertising Amendments)
Regulations 2005
2005 No. 2787
- The Control of Misleading Advertisements
Regulations 1988
1988 No. 915
- The Control of Misleading Advertisements
(Amendment) Regulations 2000
2000 No. 914
- European Directive 92/28/EEC of 31 March 1992 on
the advertising of medicinal products for human use
(now consolidated as Articles 86 to 100 of Directive
2001/83/EC)

OTHER CODES

International

- IFPMA Code of Pharmaceutical Marketing Practices
(International Federation of Pharmaceutical
Manufacturers and Associations)
- EFPIA Code of Practice on the Promotion of
Medicines
(European Federation of Pharmaceutical Industries
and Associations)
- WHO Ethical Criteria for Medicinal Drug Promotion,
Geneva 1988
(ISBN 92 4 154239 X)
(World Health Organisation)
- IPCAA Code of Conduct
(International Pharmaceutical Congress Advisory
Association)

United Kingdom

- 50 The British Code of Advertising, Sales Promotion and
Direct Marketing

(Committee of Advertising Practice/
Advertising Standards Authority)

- Code of Practice for Advertising Over-the-Counter
Medicines to Health Professionals and the Retail Trade
(Proprietary Association of Great Britain – PAGB)
- Code of Standards of Advertising Practice for Over-
the-Counter Medicines
(Proprietary Association of Great Britain – PAGB)
- BMA Handbook of Medical Ethics
(British Medical Association)
- General Medical Council ‘Good medical practice’
- Department of Health ‘Commercial sponsorship –
Ethical standards for the NHS’
- Department of Health ‘Standards of Business Conduct
for NHS Staff’
- Nursing & Midwifery Council ‘Code of professional
conduct: standards for conduct, performance and ethics’
- Royal Pharmaceutical Society of Great Britain ‘Code
of Ethics and Standards’

GUIDELINES

- Advertising and Promotion of Medicines in the UK
(2005) – The Blue Guide
(Medicines and Healthcare products Regulatory
Agency)
- includes:
Disease Awareness Campaigns Guidelines
and
Medicines which are Promoted for Use during
Pregnancy – Guidance for the Pharmaceutical Industry
- Guidance on Good Practice in the Conduct of
Economic Evaluations of Medicines
(Department of Health/ABPI)
- Guidelines for Company-Sponsored Safety Assessment
of Marketed Medicines
(Medicines and Healthcare products Regulatory
Agency/Committee on Safety of Medicines/
Royal College of General Practitioners/British
Medical Association/ABPI)
- Guidelines for Phase IV Clinical Trials (ABPI)
- Guidelines on Standards for Medical Information
Departments
(Pharmaceutical Information &
Pharmacovigilance Association)
- Relationships between the Medical Profession and the
Pharmaceutical Industry (ABPI)
- The Legal and Ethical Framework for Healthcare
Market Research
(British Healthcare Business Intelligence
Association/ABPI)

INDEX

Key

numbers refer to clauses in the Code

si refers to supplementary information to a clause in the Code

¶ followed by number refers to a paragraph in the Constitution and Procedure

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optional information – 5.7 & *si*
restricted to appearance in professional publications – 5.2 & *si*
size – 5.3

ABPI (The Association of the British Pharmaceutical Industry)
Board of Management – ¶ 1.3, ¶ 3.1, ¶ 11.4, ¶ 12, ¶ 13.4, ¶ 16.1 & ¶ 16.5
examinations – 16.3 & 16.4 & *si*

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by Appeal Board – ¶ 10.1 & ¶ 10.2
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advertising to the public – 1.1 & 20.1 & *si*

advice on Code – ¶ 19.1

all-embracing claims – 7.10 & *si*

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appeals by complainants – ¶ 7.3 & ¶ 7.4
appeals by respondent companies – ¶ 7.3 & ¶ 7.5
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references to sources when taken from published studies – 7.8 & *si*

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