



CODE OF PRACTICE
for the
PHARMACEUTICAL
INDUSTRY

2015



Bringing medicines to *life*

CODE OF PRACTICE
for the
PHARMACEUTICAL INDUSTRY
2015

together with the

PRESCRIPTION MEDICINES
CODE OF PRACTICE AUTHORITY
Constitution and Procedure

PMCPA | Prescription Medicines
Code of Practice Authority

This edition of the Code of Practice comes into operation on 1 January 2015. During the period 1 January 2015 to 30 April 2015, no 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 should be submitted to the Director of the Prescription Medicines Code of Practice Authority, 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT, telephone 020-7747 8880, facsimile 020-7747 8881, email complaints@pmcpa.org.uk.

Complaints made under the Code 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.

CODE OF PRACTICE

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PHARMACEUTICAL INDUSTRY

2015

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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 over 50 years ago, in October 1958, 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 first ABPI Code of Practice. The Code covers the promotion of medicines for prescribing to both health professionals and other relevant decision makers. It also includes requirements for interactions with health professionals. 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 other relevant decision makers is carried out within a robust framework to support high quality patient care. As well as covering promotional material, it controls samples, meetings, promotional aids, the provision of medical and educational goods and services, outcome or risk sharing agreements, patient access schemes, joint working between the pharmaceutical industry and the NHS, the conduct of non-interventional studies, the use of health professionals and other relevant decision makers as consultants and transfers of value to health professionals, other relevant decision makers and healthcare organisations. 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 Practice
- the European Federation of Pharmaceutical Industries and Associations' (EFPIA) Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals
- the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations
- the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations
- the World Health Organisation's Ethical Criteria for Medicinal Drug Promotion
- Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as amended by Directive 2004/27/EC
- The Human Medicines Regulations 2012 (2012 No.1916), as amended.

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 'Good Medical Practice', the General Pharmaceutical Council 'Standards of conduct, ethics and performance' and the Nursing & Midwifery Council 'Standards of conduct, performance and ethics for nurses and midwives'. Patient organisations are likely to be covered by Charity

Commission rules as well as their own codes. The pharmaceutical industry takes note of all relevant codes and guidance as well as the ABPI Code.

Transparency

The industry recognises that transparency is an important means of building and 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. The industry's global agreement to disclose certain clinical trial data is another example of the industry's commitment to transparency. Companies also have to publish the summary details and results of non-interventional studies as well as the monetary value of certain support to patient organisations.

Other transparency changes, effective in 2012 and 2013, included disclosure of the total amount of fees paid to consultants for certain services and the total amounts paid to sponsor attendance at meetings organised by third parties. As set out in the 2014 Code, in 2015 and 2016 transparency will be extended in relation to fees and sponsorship provided to health professionals and healthcare organisations, including naming the recipients in many instances.

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, pharmaceutical and nursing 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 pharmaceutical sector makes a significant contribution to the UK economy and generates an annual trade surplus of £2.8 billion. One sixth of the world's most popular prescription medicines were developed in the UK.

Investment into researching and developing new products in the UK is now running at over £4.2 billion a year and each new medicine takes over 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 represents companies which supply 90 per cent of all medicines used by the National Health Service, and are researching and developing 90 per cent of the current medicines pipeline.

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, the Royal College of Nursing, the Medicines and Healthcare Products Regulatory Agency of the Department of Health, the Competition and Markets Authority and the Serious Fraud Office. Anyone is welcome to send suggestions for amendments or additions to the Code to the PMCPA.

It is a condition of membership of the ABPI to abide by the Code in both the spirit and the letter. The Code applies to both members and affiliate members of the ABPI. Companies which are not members of the ABPI may give their formal agreement to abide by the Code and accept the jurisdiction of the PMCPA and over sixty have done so. 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 PMCPA 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 its website www.pmcpa.org.uk or are supplied on request.

Complaints 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 in its Code of Practice Review and on its website. The PMCPA also 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, 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT, telephone 020-7747 8880, facsimile 020-7747 8881, email complaints@pmcpa.org.uk.

PROVISIONS OF THE 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 other relevant decision makers.

The Code also applies to a number of areas which are non-promotional, including information made available to the 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 administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

It includes:

- journal and direct mail advertising
- the activities of representatives including any electronic or printed material used by them
- 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 or video recordings in any format, broadcast media, non-print media, the Internet, interactive data systems, social media and the like.

It does not include:

- replies made in response to individual enquiries from members of the health professions or other relevant decision makers 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

- price lists relating to unlicensed medicines, provided they include no product claims and they make clear that the products are unlicensed
- information supplied by pharmaceutical companies to national public organisations, such as the National Institute for Health and Care 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 administer, prescribe, purchase, recommend or supply a medicine.

1.5 The term 'other relevant decision makers' particularly includes those with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who are not health professionals.

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

1.7 The term 'representative' means a representative calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines.

1.8 The term 'promotional aid' means a non-monetary gift made for a promotional purpose.

1.9 The term 'healthcare organisation' means either a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more health professionals or other relevant decision makers provide services.

1.10 The term ‘transfer of value’ means a direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines. A direct transfer of value is one made directly by a company for the benefit of a recipient. An indirect transfer of value is one made by a third party on behalf of a company for the benefit of a recipient where the identity of the company is known to, or can be identified by, the recipient.

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

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

Clause 1 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 other relevant decision makers 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 other relevant decision makers 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 declarations of sponsorship in Clause 9.10, clinical trials and non-interventional studies in Clause 13, certain aspects of the provision of medicines and samples in Clause 17, donations, grants and fees for services in Clauses 19.2 and 21, the use of consultants in Clause 23, the provision of information to the public in Clause 26 and relations with patient organisations in Clause 27.

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 Market Extension

Activities which are designed to enlarge the market in a particular therapeutic area, such as disease awareness campaigns, are permitted, provided that these are carried out in a manner compatible with the Code.

Clause 1.1 Joint Working

Joint working with the NHS and others is permitted if carried out in a manner compatible with the Code.

Joint working is where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery.

The Department of Health has issued to the NHS Best practice guidance on joint working between the NHS and pharmaceutical industry and other relevant commercial organisations. A toolkit, Moving beyond sponsorship: joint working between the NHS and the pharmaceutical industry has been issued by the Department of Health and the ABPI. The ABPI has produced guidance notes on joint working between pharmaceutical companies and the NHS and others for the benefit of patients.

The conduct of joint working is dealt with in Clause 20 and its supplementary information.

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. The identification of the country in which a journal is ‘produced’ is based on factors such as where it is compiled and edited, and where it is typeset, printed and bound, rather than on factors such as the location of the head office of the publisher.

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 advising that 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 Practice should be borne in mind.

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

The promotion of medicines to the public for self medication is covered by the Consumer Code of the Proprietary Association of Great Britain (PAGB) (www.pagb.co.uk). The PAGB also has a Professional Code which applies to advertising involving over-the-counter medicines aimed wholly or mainly at persons qualified to prescribe or supply and appropriate administrative staff, where the object of the advertising is to influence sales and/or recommendations to the public.

Clause 1.1 Promotion to Other Relevant Decision Makers

The provisions of the Code apply in their entirety to the promotion of medicines to other relevant decision makers except where the text indicates otherwise. This would include administrative staff where appropriate. For example, the prescribing information required under Clause 4 must be

included in promotional material provided to other relevant decision makers 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 11.1 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 other relevant decision makers 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 1.2 Price Lists for Unlicensed Medicines

Price lists of unlicensed medicines which include no product claims and make clear that the products are unlicensed can be sent to health professionals and other relevant decision makers at reasonable intervals or in response to enquiries. They must not be used proactively in a manner which could be seen to be promoting unlicensed medicines, such as by displaying them on exhibition stands.

Clause 1.7 Representatives

'Medical representatives' and 'generic sales representatives' are distinguished in the supplementary information to Clause 16.3 relating to examinations for representatives.

Clause 1.9 Healthcare Organisations

If a healthcare organisation consists of only one health professional or other relevant decision maker then it would be subject to the requirements in the Code regarding individual health professionals.

Clause 1.10 Excluded Disclosures

The following are not transfers of value for the purposes of the Code:

- transfers of value that are solely related to over-the-counter medicines
- ordinary course purchases and sales of medicines by and between a company and a health professional or a healthcare organisation including package deals as defined in the supplementary information to Clause 18.1
- samples of medicines provided in accordance with Clause 17

- transfers of value provided in accordance with Clauses 18.2 and 18.3
- subsistence provided to health professionals in accordance with Clause 22.1.

Clause 1.11 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 other relevant decision makers 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 other relevant decision makers are involved. Details of the various codes can be found at www.efpia.eu or www.ifpma.org.

By 'company' is meant any legal entity that organises 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 organisation.

In the event of a conflict of requirements the more restrictive requirements would apply. There is a potential exception with regard to the limits for subsistence set in European countries where the national association is a member of EFPIA and thus covered by EFPIA Codes as referred to in the supplementary information to Clause 22.2.

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.

Companies must take reasonable steps to ensure that any other parties that they commission to design, implement or engage in activities covered by the Code but which do not act on behalf of the company, and are therefore not covered by Clause 1.2, for example joint ventures or licensees, comply with the Code.

Clause 1.12 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

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 Supplementary Information

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 the attendees from countries outside the UK in which the product is licensed*
- *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*

Clause 2 Supplementary Information

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, unacceptable payments, 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.

prescribing information must be readily available for a medicine authorized in the UK even though it will not refer to the unlicensed indication

- *the names must be given of countries in which the medicine or indication is authorized which must include at least one major developed country 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 which May Significantly Affect Expenditure

NHS organisations and others involved in the purchase of medicines need to estimate their likely budgets in advance 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.

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 be in breach of the Code for them to be promoted. Companies wishing to provide advance notification must ensure that information is also provided wherever possible for inclusion in national horizon scanning databases. Non promotional information can be provided as advance notification but it must:

- relate to:*
 - a product which contains a new active substance, or*
 - a product which contains an active substance prepared in a new way, such as by the use of biotechnology, or*
 - a product which is to have a significant addition to the existing range of authorized indications, or*
 - a product which is to have a novel and innovative means of administration*
- only be directed to those responsible for making policy decisions on budgets and not those expected to prescribe*

- iii) state whether or not a new medicine or a change to an existing medicine is the subject of a marketing authorization in the UK
- iv) state the likely cost or savings and budgetary implications which must be such that they will significantly change the organisation's likely expenditure
- v) be factual and 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

The information provided must not:

- i) be promotional in style – product 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 stylised or used to excess
- ii) include mock up drafts of either summaries of product characteristics or package leaflets.

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

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).

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.

4.2 The prescribing information consists of the following:

- the legal classification of the product
- 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
- and
 - i) the name of the medicine (which may be either a brand name or a non-proprietary name)
 - ii) 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
 - iii) at least one authorized indication for use consistent with the summary of product characteristics

- iv) 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
- v) a succinct statement of common adverse reactions likely to be encountered in clinical practice, serious adverse reactions 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 adverse reactions
- vi) 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
- vii) 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
- viii) the date the prescribing information was drawn up or last revised.

The summary of product characteristics may be provided instead of i-viii above.

If the summary of product characteristics is not used then the information specified above in relation to iv, v, and vi 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 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.

For electronic advertisements 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.

4.4 In the case of digital material such as advertisements in electronic journals, emails, electronic detail aids and such like, the prescribing information as required by Clause 4.1 may be provided either:

- by inclusion in the digital material itself or
- by way of a clear and prominent direct single click link.

4.5 In the case of audio-visual material such as films, DVDs 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.

4.6 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.

4.7 In the case of a printed 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 page 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 must include the prominent statement 'Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to [relevant pharmaceutical company]'.

4.11 When required by the licensing authority, all promotional material must show an inverted black equilateral triangle to denote that additional monitoring is required in relation to adverse reactions.

Clause 4 Supplementary Information

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 separate summary of product characteristics is not sufficient to conform with the provisions of this clause.

There may be instances where reproducing the summary of product characteristics will not be an acceptable way to fulfil the requirement for prescribing information. For example, Clause 6.3 limits advertising in journals for a particular product to two pages.

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

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 '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
- boldening headings and starting each section on a new line aids legibility.

Clauses 4.1 and 4.9 Date of Prescribing Information and Promotional Material

If the summary of product characteristics is not used then the date that the prescribing information was last drawn up or last revised must be included (Clause 4.2 viii).

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 equilateral triangle on its promotional material then the black triangle symbol must also appear adjacent to the product name (see Clause 4.11). The size must be such that it is easily

readable. The requirement of Clause 12.1 that promotional material and activities must 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 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 4.4 Use of Links for Prescribing Information

When digital material provides the reader with a link to prescribing information on another website then such a link should only be included for use when the material is generally expected to be viewed online, for example, advertisements in electronic journals or electronic detail aids when used remotely and the like. This is to ensure that at the time of reading the link is active and will provide readers with the necessary information. When material is more likely to be viewed offline, such as electronic detail aids to be used by representatives when visiting health professionals, emails and the like, then the requisite information must be provided as part of the item itself or as a link that does not require the reader to be online.

Clause 4.5 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 4.10 Adverse Event Reporting

A telephone number or email address 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.

In the event that the website address given in Clause 4.10 is changed by the Medicines and Healthcare Products Regulatory Agency, companies may use a statement incorporating the new address as soon as the change is made and must use the new address within one year of the change.

Clause 4.11 Black Triangle Symbol

The agreement between the then 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.

Digital communications are also covered by this requirement and the black triangle symbol should be located adjacent to the first mention of the product as this is likely to be considered the most prominent display of the name of the product. The size must be such that it is easily readable.

Summaries of product characteristics and package leaflets are excluded from the definition of 'promotion' in the Code by Clause 1.2. However it should be noted that EU legislation now requires the black triangle symbol to appear on summaries of product characteristics and on package leaflets. The size of the black triangle on these documents has to be proportionate to the font size of the subsequent text with a minimum length of 5mm per side. The EU requirements do not apply to promotional material. Obligatory explanatory wording is also required.

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 ie publications sent or delivered wholly or mainly to members of the health professions and/or other relevant decision makers. A loose insert in such a publication cannot be an abbreviated advertisement.

Abbreviated advertisements may contain only the information specified in Clauses 5.4, 5.5, 5.6, 5.7 and 5.8.

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
- 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
- abbreviated advertisements must include the statement 'Information about this product, including adverse reactions, precautions, contra-indications and method of use can be found at [the address of the website referred to below]' and state that prescribers are recommended to consult the summary of product characteristics before prescribing.

The following information must be provided on the website referred to above:

either, the information set out in Clauses 4.2 and 4.3 (except that 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 most prominent display of the brand name in a size such that the information is readily readable and information about cost as required by Clause 4.2 need not be included on the website where the abbreviated advertisement appears only in journals printed in the UK which have more than 15 per cent of their circulation outside the UK),

or, 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 the prominent statement 'Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to [relevant pharmaceutical company]'.

5.7 When required by the licensing authority, abbreviated advertisements must show an inverted black equilateral triangle to denote that additional monitoring is required in relation to adverse reactions.

5.8 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.

5.9 Marketing authorization numbers and references must not be included in abbreviated advertisements.

Clause 5 Supplementary Information

Clause 5.2 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.

DVDs and suchlike sent to doctors etc may be considered professional publications and an abbreviated advertisement may be included on a box containing a DVD. 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, 5.7, 5.8 and 5.9 Permitted Information

The contents of abbreviated advertisements are restricted as set out in Clauses 5.4, 5.5, 5.6, 5.7, 5.8 and 5.9 and the following information should not therefore be included in abbreviated advertisements:

- 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, 5.7, 5.8 and 5.9.

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 5.6 Adverse Event Reporting

A telephone number or email address for the relevant department of the company may be included.

In the event that the website address given in Clause 5.6 is changed by the Medicines and Healthcare Products Regulatory Agency, companies may use a statement incorporating the new address as soon as the change is made and must use the new address within one year of the change.

Clause 5.7 Black Triangle Symbol

The agreement between the then 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.

It should be borne in mind that abbreviated advertisements

must be no larger than 420 square centimetres in size. In abbreviated advertisements of no more than 310.8 square centimetres (A5) each side should be no less than 3mm. In abbreviated advertisements larger than A5 (but no larger than 420 square centimetres) each side should be no less than 5mm.

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.

Clause 6 Supplementary Information

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 'wraparounds' must not have a greater surface area than that outlined for loose inserts under Clause 6.2.

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. An 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

Information, Claims and Comparisons

7.1 Upon reasonable request, a company must promptly provide members of the health professions and other relevant decision makers 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 members of the health professions or other relevant decision makers.

The validity of indications approved in the marketing authorization can be substantiated by provision of the summary of product characteristics.

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 other relevant decision makers.

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 adverse reactions must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no adverse reactions, 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 promoted, for more than twelve months in the UK.

Clause 7 Supplementary Information

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 adverse reactions 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

- *reference to absolute risk and relative risk. Referring only to relative risk, especially with regard to risk reduction, can make a medicine appear more effective than it actually is. In order to assess the clinical impact of an outcome, the reader also needs to know the absolute risk involved. In that regard relative risk should never be referred to without also referring to the absolute risk. Absolute risk can be referred to in isolation*

- *economic evaluation of medicines. 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

- *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*

- *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 a clinical trial is used companies must ensure that where necessary that trial has been registered and the results disclosed in accordance with Clause 13.1.

Clause 7.6 References

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

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 contraindications. 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' 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.

Similarly, care needs to be taken with the use of 'unique'. Although 'unique' may sometimes be used to describe some clearly defined special feature of a medicine, often 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.

Clause 8 Supplementary Information

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.

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 Commission on Human Medicines, the Medicines and Healthcare Products Regulatory 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 material must be avoided.

Informational or educational materials must be inexpensive, directly relevant to the practice of medicine or pharmacy and directly beneficial to the care of patients.

9.8 Postcards, other exposed mailings, envelopes or wrappers must not carry matter which might be regarded as advertising to the public, contrary to Clause 26.1.

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.

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

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 9 Supplementary Information

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 use of inappropriate language abbreviations or emoticons particularly in digital communications*
- *the provision of private prescription forms preprinted with the name of a medicine.*

Clause 9.5 MHRA Drug Safety Update

Where factual safety information given in promotional material is based on advice in the MHRA Drug Safety Update, the information can be referenced to that publication.

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.

Clause 9.9 Unsubscribing to emails

Where permission to use emails for promotional purposes has been given by a recipient, each email sent should inform the recipient as to how to unsubscribe to them.

Clause 9.9 Responding to emails

An unsolicited enquiry received by email or an unsolicited enquiry received by post which includes an email address can be responded to by email without specific permission, consent to do so being implied in such circumstances. There is no need to inform recipients as to how to unsubscribe to an email response to an enquiry.

Clause 9.9 Remote Detailing

When promotion is carried out remotely, such as by telephone call, web chat or other online calls, prior permission from the recipient must be obtained in advance or at the start of the contact or call. In setting up the contact or call, full details must be given of the company the caller will represent, their role and the purpose of the call. Arrangements made to discuss a specific product should be adhered to.

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.

The wording of the declaration must be unambiguous so that readers will immediately understand the extent of the company's involvement and influence over the material. This is particularly important when companies are involved in the production of material which is circulated by an otherwise wholly independent party, such as supplements to health professional journals.

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

Provision of Reprints and the Use of Quotations

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

10.2 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.

10.3 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.

10.4 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 10 Supplementary Information

Clause 10.1 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 10.2 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 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 10.4 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 11

Distribution of Material

11.1 Material should only be sent or distributed to those categories of persons whose need for, or interest in, it can reasonably be assumed.

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

11.3 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.

Clause 11 Supplementary Information

Clause 11.1 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 other relevant decision makers.

Clause 11.2 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.

In the first six months following the launch of a new medicine, a health professional may be sent an initial mailing giving 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 as can mailings about price changes which contain no product claims.

The limitations on frequency of mailings do not apply to emails as these can only be sent with the prior permission of the recipient.

Clause 12

Disguised Promotion

12.1 Promotional material and activities must not be disguised.

12.2 Market research activities, clinical assessments, post-marketing surveillance and experience programmes, post-authorization studies (including those that are retrospective in nature) and the like must not be disguised promotion. They must be conducted with a primarily scientific or educational purpose.

Clause 12 Supplementary Information

Clause 12.1 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. Similarly, promotional material sent electronically such as emails must not give the impression that it is non promotional. In addition the identity of the responsible pharmaceutical company must be obvious.

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 12.2 Non-Interventional Studies of Marketed Medicines

The conduct of non-interventional studies of marketed medicines is dealt with in Clause 13.

Clause 12.2 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 the Legal & Ethical Guidelines 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. 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 13

Clinical Trials and Non-Interventional Studies of Marketed Medicines

13.1 Companies must disclose details of clinical trials in accordance with the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature.

13.2 A non-interventional study of a marketed medicine is defined as a study where the medicine is prescribed in the usual manner in accordance with the terms of its marketing authorization. The assignment of the patient to a particular therapeutic strategy is not decided by a study protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures are applied to the patients and epidemiological methods are used for the analysis of collected data.

13.3 Companies must publish the summary details and results of non-interventional studies of marketed medicines in a manner consistent with their parallel obligations with respect to clinical trials.

13.4 Non-interventional studies that are prospective in nature and involve the collection of patient data must be conducted for a scientific purpose. They must comply with the following criteria:

- there must be a written protocol and written contracts between the health professionals and/or the institutes at which the study will take place and the pharmaceutical company sponsoring the study, which specify the nature of the services to be provided and the payment for those services
- any remuneration must be reasonable and reflect the fair market value of the work
- in countries where ethics committees are prepared to review such studies, the study protocol must be submitted to the ethics committee for review
- data protection legislation must be complied with
- the study must not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine
- the company's scientific service must approve the protocol and must supervise the conduct of the study
- the study results must be analysed and summaries must be made available within a reasonable period of time to the company's scientific service, which service shall maintain records of such reports; the summary report should be sent to health professionals who participated in the study. If the study results are important for the assessment of benefit/risk, the summary report should be immediately forwarded to the relevant competent authority

- sales representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the company's scientific service which will also ensure that the representatives are adequately trained for the role; such involvement must not be linked to the promotion of any medicine.

Clause 13 Supplementary Information

Clause 13 Good Pharmacovigilance Practices

Attention is drawn to the 'Good pharmacovigilance practices' page on the European Medicines Agency website. (www.ema.europa.eu)

Clause 13.1 Details of Clinical Trials

This clause requires the provision of details about ongoing clinical trials (which must be registered within 21 days of initiation of patient enrolment) and the results of completed trials for medicines licensed for use and commercially available in at least one country. Further information can be found in the current Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases and the current Joint Position on the Publication of Clinical Trial Results in the Scientific Literature, both at www.ifpma.org/en/ethics/clinical-trials-disclosure.html.

Companies must include on the home page of their website information as to where details of their clinical trials can be found.

Details about clinical trials must be limited to factual and non-promotional information. Such information must not constitute promotion to health professionals, other relevant decision makers or the public.

Clause 13.3 Publication of Details and Results

This requirement applies to non-interventional studies completed on and after 1 May 2011 with which a UK company has had any involvement. Companies are, however, encouraged to publish details and results of such studies completed prior to that date.

Clause 13.4 Other Studies Covered by Clause 13.2

Companies are encouraged to comply with Clause 13.4 for all other types of studies covered by Clause 13.2, including epidemiological studies and registries and other studies that are retrospective in nature. In any case, such studies are subject to Clause 21.

Clause 13.4 Approval and Supervision

The approval and supervision of non-interventional studies are dealt with in Clause 25.2.

Clause 13.4 Date of Implementation

Companies must comply with Clause 13.4 in relation to non-interventional studies that are completed on or after 1 July 2008. Companies are encouraged to comply in relation to studies completed prior to that date.

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 a pharmacist registered in the UK or alternatively, in the case of a product for dental use only, a UK registered dentist.

The second person certifying on behalf of the company must be a senior official of the company or an appropriately qualified person.

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 unless the company's only involvement is to support a speaker to present at the meeting.

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
- material relating to working with patient organisations as described in Clause 27 and its supplementary information

- material relating to joint working between the NHS and the pharmaceutical industry as described in Clause 20 and its supplementary information

- material relating to patient support programmes involving the provision to health professionals of items to be passed on to patients as described in Clause 18.2 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 19.1 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 Advertising Standards Unit, Vigilance and Risk Management of Medicines 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 regulations relating to advertising 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 material covered by Clause 14.3 above must certify that the signatories have examined the final form of the material and that in their belief it complies with the Code.

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 regulations relating to advertising 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 regulations relating to advertising 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.

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.

The certificates for material covered by Clause 14.3 above shall be preserved for not less than three years after the final use of the material and companies shall produce them on request from the Medicines and Healthcare Products Regulatory Agency or the Prescription Medicines Code of Practice Authority.

Clause 14 Supplementary Information

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. Paper or electronic copies of certificates and the final form of material etc must be preserved in order to comply with Clause 14.6.

When certifying material where the final form is to be printed companies can certify the final electronic version of the item to which no subsequent amendments will be made. When such material is printed the company must ensure that the printed material cannot be used until any one of the company's signatories has checked and signed the item in its final form. In such circumstances the material will have two certificates and both must be preserved.

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 and relevant representatives' briefing materials. Promotional aids must also be certified. Although not strictly promotional material they are

used for a promotional purpose.

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 53 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 Certifying Digital Material

When certifying dynamic content for websites, care must be taken to ensure the dynamic content meets the requirements of the Code both as a standalone item and within the context in which it appears. The final form of digital material might not be static.

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.

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 or other arrangements where companies work together, such as joint working projects, the companies concerned can agree to have only two final signatories to certify on behalf of all the companies. This must all be agreed beforehand and the Medicines and Healthcare Products Regulatory Agency and the Prescription Medicines Code of Practice Authority must be informed in advance who the signatories will be. In the event of a complaint about material certified in this way each company involved in the project/activity would be responsible 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 14.3 Non-Interventional Studies

The examination of non-interventional studies is dealt with in Clause 25.2 and is not covered by Clause 14.

Clause 14.4 Notification of Signatories

The names and qualifications of signatories and changes to them should be notified to the Medicines and

Healthcare Products Regulatory Agency by email to signatories.advertising@mhra.gsi.gov.uk.

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.

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 and other relevant decision makers in hospitals and NHS and other organisations, 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 25.1 any information which they receive in relation to the use of the medicines which they promote, particularly reports of adverse reactions.

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.

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 Supplementary Information

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 and electronic 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 or 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 and 16.3.

Clause 15.3 Hospitality and Payments for Meetings

Attention is drawn to the requirements of Clauses 18 and 22 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 other relevant decision makers.

Meetings organised for groups of doctors, other health professionals and/or other relevant decision makers 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.

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 to health professionals or other relevant decision makers should explain that there is no obligation to grant the representative an interview when the items are 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 or subterfuge to gain an interview.

Clause 15.3 Health Professionals' Codes of Conduct

The General Medical Council is the regulatory body for doctors and is responsible for giving guidance on standards of professional conduct and on medical ethics. In its guidance, the GMC advises doctors that 'You must not allow any interests you have to affect the way you prescribe for, treat, refer or commission services for patients' and 'You must not ask for or accept – from patients, colleagues or others – any inducement, gift or hospitality that may affect or be seen to affect the way you prescribe for, treat or refer patients or commission services for patients. You must not offer these inducements'.

The General Pharmaceutical Council is the regulatory body for pharmacists and pharmacy technicians. The Council's Standards of conduct, ethics and performance state 'Do not ask for or accept gifts, rewards or hospitality that may affect, or be seen to affect, your professional judgement'.

The Code of the Nursing & Midwifery Council, Standards of conduct, performance and ethics for nurses and midwives, states 'You must not abuse your privileged position for your

own ends' and 'You must ensure that your professional judgement is not influenced by any commercial considerations'.

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.

When briefing representatives companies should distinguish clearly between expected call rates and expected contact rates. Contacts include those at group meetings, visits requested by doctors or other prescribers, visits in response to specific enquiries and visits to follow up adverse reaction reports. Targets must be realistic and not such that representatives breach the Code in order to meet them.

Clause 15.8 Provision of Summary of Product Characteristics

The requirement to provide a copy of the summary of product characteristics can be met by the provision of an electronic copy if the recipient agrees.

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, and others retained by way of contract, concerned in any way with the preparation or approval of material or activities covered by the Code must be fully conversant with the Code and the relevant laws and regulations.

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

16.3 Representatives must take an appropriate examination within their first year of employment as a representative and must pass it within two years of starting such employment.

To be acceptable, an examination must have been accredited to at least Level 3 by an external awarding body recognised by Ofqual.

An appropriate examination for medical representatives is one that requires a broad understanding of body systems, diseases and treatments, the development of new medicines and the structure and function of the NHS and of the pharmaceutical industry. Such an examination must be a Diploma (at least 37 credits or equivalent learning hours).

An appropriate examination for generic sales representatives is one that requires a broad understanding of body systems, the structure and function of the NHS and of the pharmaceutical industry. Such an examination must be a Certificate (at least 13 credits or equivalent learning hours).

An appropriate examination can be either the relevant ABPI examination (for medical or generic sales representatives) or an examination of at least the same standard as the ABPI examinations and covering similar content and learning material as the corresponding ABPI examination.

16.4 Details of the numbers of representatives who have passed an examination, together with the examination status of others, must be provided to the Prescription Medicines Code of Practice Authority on request.

Clause 16 Supplementary Information

Clause 16.1 Scope of the Code

The materials/activities covered by the Code include promotional materials and activities listed in Clause 1.1, information provided to health professionals and other relevant decision makers and information provided to the public, patients and patient organisations.

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 Examinations

The ABPI offers two examinations and further details can be obtained from the ABPI.

Examinations may also be offered by other providers. A company using an examination provider other than the ABPI must be able to demonstrate that its examinations are at least equivalent to those offered by the ABPI. The syllabus studied should be mapped to and meet the requirements in the published ABPI standards. The assessment must be under invigilated examination conditions.

The ABPI Medical Representatives Examination is appropriate for 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 ABPI Generic Sales Representatives Examination is

appropriate for representatives who promote medicines primarily on the basis of price, quality and availability to those who do not prescribe medicines.

The ABPI examinations for medical representatives and generic sales representatives are based on material published by the ABPI.

Persons who have passed the ABPI Medical Representatives Examination or similar whose duties change to those specified for generic sales representatives do not need to take another examination. However, persons who have passed the ABPI Generic Sales Representatives Examination or similar whose duties change to those specified for medical sales representatives must take an appropriate examination within one year of their change of duties and pass it within two years.

Clause 16.3 Introduction of Accredited Examinations

Representatives commencing such employment on or after 1 October 2014 must take an accredited examination. It is recommended that representatives commencing such employment on or after 1 January 2014 but on or before 30 September 2014 also take an accredited examination.

The ABPI will offer accredited examinations by January 2014 and will cease to offer its unaccredited examinations on 31 December 2015.

A candidate who has passed part of an unaccredited ABPI examination will have to complete that examination by 31 December 2015 or transfer to an accredited examination. The limitations on time within which representatives must pass an examination, which are set out in Clause 16.3 and its supplementary information, must be borne in mind.

A candidate who has taken part of an ABPI examination who wishes to transfer to a new provider will have to take the whole of the new provider's examination. Similarly, a candidate who has taken part of an alternative provider's examination who wishes to transfer to an ABPI examination will have to take the whole of that examination. This will not apply if it can be demonstrated that the units already passed are equivalent to those of the new provider whether that is an ABPI examination or an alternative provider's examination.

Clause 16.3 Information from Examination Provider

A company must take steps to ensure that its examination provider would respond to requests for information from the Authority.

Clause 16.3 Time Allowed to Pass an Examination

Prior to passing an appropriate 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, work eighteen months with one company and eighteen months with another and so on, thus avoiding an examination. Maternity or paternity leave does not count towards the specified time periods.

In the event of extenuating circumstances, such as prolonged illness or no or inadequate opportunity to take an appropriate 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 an appropriate examination within a reasonable time.

Similarly, in the event of failure to take an appropriate examination within the first year, the Director may agree to an extension, subject to the representative taking an examination within a reasonable time.

An application for an extension should be made on a form available from the Prescription Medicines Code of Practice Authority. It should preferably be made by the company rather than the representative.

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.

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 other relevant decision makers.

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

Samples of a particular medicine may be provided to a health professional for no longer than two years after that health professional first requests samples of it.

Notwithstanding the above, when a new medicine is marketed which is an extension of an existing product, samples of that new medicine can be provided as above. A 'new medicine' in this context is a product for which a new marketing authorization has been granted, either following the initial application or following an extension application for a new indication that includes new strengths and/or dosage forms. Extension of a marketing authorization to include additional strengths and/or dosage forms for existing indications or to include additional pack sizes is not regarded as leading to new medicines.

17.3 Samples may only be supplied in response to written requests which have been signed and dated. An electronic signature is acceptable.

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 to 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. Systems must clearly establish, for each health professional, the number of samples supplied in accordance with Clause 17.2.

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 public for promotional purposes.

17.12 Samples must not be provided simply as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. Samples must not be given for the sole purpose of treating patients.

Clause 17 Supplementary Information

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. This is because they are not for the purposes described above.

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

The supply of a product which is not a medicine because it does not contain the active ingredient normally present is not regarded as the supply of a sample.

Clause 17 Starter Packs

The provision of starter packs is not permitted. Starter packs were 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.

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

Prohibition on Inducements and Inappropriate Payments, the Provision of Items for Patients, Health Professionals and Other Relevant Decision Makers, Agreements to Benefit Patients such as Outcome Agreements and Patient Access Schemes

18.1 No gift, pecuniary advantage or benefit may be supplied, offered or promised to members of the health professions or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, subject to the provisions of Clauses 18.2 and 18.3.

18.2 Health professionals may be provided with items which are to be passed on to patients and which are part of a formal patient support programme, the details of which have been appropriately documented and certified in advance as required by Clause 14.3.

The items provided must be inexpensive and directly benefit patient care. They may bear the name of the company providing them. They must not be given out from exhibition stands. They must not be given to administrative staff unless they are to be passed on to a health professional.

18.3 Health professionals and other relevant decision makers attending company organised scientific meetings and conferences, promotional meetings and the like may be provided with inexpensive notebooks, pens and pencils for use at those meetings. They must not bear the name of any medicine or any information about medicines but may bear the name of the company providing them. If pens and pads are provided in conference bags at third party organised meetings then these must not include the names of the donor companies, the name of any medicine or any information about medicines.

Clause 18 Supplementary Information

Clause 18.1 Health Professionals' Codes of Conduct

The General Medical Council is the regulatory body for doctors and is responsible for giving guidance on standards of professional conduct and on medical ethics. In its guidance, the GMC advises doctors that 'You must not allow any interests you have to affect the way you prescribe for, treat, refer or commission services for patients' and 'You must not ask for or accept – from patients, colleagues or others – any inducement, gift or hospitality that may affect or be seen to affect the way

you prescribe for, treat or refer patients or commission services for patients. You must not offer these inducements'.

The General Pharmaceutical Council is the regulatory body for pharmacists and pharmacy technicians. The Council's Standards of conduct, ethics and performance state 'Do not ask for or accept gifts, rewards or hospitality that may affect, or be seen to affect, your professional judgement'.

The Code of the Nursing & Midwifery Council, Standards of conduct, performance and ethics for nurses and midwives, states 'You must not abuse your privileged position for your own ends' and 'You must ensure that your professional judgement is not influenced by any commercial considerations'.

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.

Clause 18.1 Package Deals

Clause 18.1 does not prevent the offer of package deals which are commercial arrangements whereby the purchase of a particular medicine is linked to the provision of certain associated benefits as part of the purchase price, such as apparatus for administration, the provision of training on its use or the services of a nurse to administer it. The transaction as a whole must be fair and reasonable and the associated benefits must be relevant to the medicine involved.

Clause 18.1 Outcome or Risk Sharing Agreements

Clause 18.1 does not preclude the use of outcome or risk sharing agreements where a full or partial refund of the price paid for a medicine, or some other form of recompense, is due if the outcome of the use of the medicine in a patient fails to meet certain criteria. That is to say its therapeutic effect does not meet expectations. Clear criteria as to when a refund or other recompense would be due must be settled in advance and set out in the agreement. Any refund or recompense must always go to the relevant NHS or other organisation and never to individual health professionals or practices etc.

Clause 18.1 Patient Access Schemes

Patient access schemes are acceptable in principle under the Code but they must be carried out in conformity with its requirements.

The 2014 Pharmaceutical Price Regulation Scheme describes patient access schemes as schemes proposed by a pharmaceutical company and agreed with the Department of Health (with input from the National Institute for Health and Care Excellence) in order to improve the cost-effectiveness of

a medicine and enable patients to receive access to cost-effective innovative medicines. Corresponding arrangements apply in the devolved nations.

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.

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 18.1 Payments to Individuals

Any payment to an individual for an activity that is ruled in breach of Clause 12.2 and/or Clause 23 is likely to be viewed as an unacceptable payment and thus in breach of Clause 18.1.

Clause 18.1 Long term or Permanent Loan

The requirements of Clause 18.1 cannot be avoided by providing health professionals or practices etc with items on long term or permanent loan. Such items will be regarded as gifts and subject to the requirements of this clause.

Clause 18.1 Competitions and Quizzes

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

This does not preclude the use at promotional meetings of quizzes which are intended to gauge attendees' knowledge of the subject matter of the meetings, provided that such quizzes are non-promotional in nature and are bona fide tests of skill that recognise the professional standing of the audience and no prizes are offered. To be acceptable a quiz must form part of the meeting's formal proceedings. Exhibition stands must not be included in any way in the conduct of a quiz.

Clause 18.1 Promotional Aids

A promotional aid is defined as a non-monetary gift made for a promotional purpose. Promotional aids may be given to health professionals and other relevant decision makers only in accordance with Clause 18.3. Health professionals may, however, be provided with items which are to be passed on to patients in accordance with Clause 18.2.

Items to be passed on to patients may bear the name of a medicine and/or information about medicines only if such detail is essential for the proper use of the item by patients.

Items for the personal benefit of health professionals or other relevant decision makers must not be offered or provided.

Gifts such as coffee mugs, stationery, computer accessories, diaries, calendars and the like are not acceptable. Gifts of items for use with patients in the clinic, surgery or treatment room etc, such as surgical gloves, nail brushes, tongue depressors, tissues and the like, are also not acceptable. Items such as toys and puzzles intended for children to play with while waiting must not be provided. Gifts of items for use in the home or car are unacceptable.

Pharmaceutical companies cannot give diaries and desk pads etc to health professionals and appropriate administrative staff but there is nothing to prevent them being given by other parties which are not pharmaceutical companies. Advertisements for prescription medicines must not appear on any items, such as diaries and desk pads, which pharmaceutical companies could not themselves give.

Literature such as leaflets, booklets and textbooks about medicines and their uses, which is intended for patients, can be provided to health professionals for them to pass on. They are not considered to be promotional aids but they must comply with relevant requirements of the Code, in particular Clause 26 and its supplementary information. A story-book for young patients about a product or a disease could be provided for relevant patients.

Clause 18.1 DVDs

Clause 18.1 does not preclude the provision to health professionals and other relevant decision makers of inexpensive DVDs etc which bear educational or promotional material compliant with the Code, provided that they cannot be used by the recipient to store other data.

Clause 18.1 Memory Sticks

Clause 18.1 does not preclude the provision to health professionals and other relevant decision makers of inexpensive memory sticks which bear educational or promotional material compliant with the Code, provided that their storage capacity is commensurate with the amount of data to be stored.

Clause 18.1 Textbooks

Textbooks must not be given to health professionals as promotional aids. In appropriate circumstances independently produced medical/educational publications such as textbooks could be given for health professionals to use in accordance with Clause 19.1 – Medical and Educational Goods and Services – but they must not be given to individuals.

Clause 18.2 Patient Support Items

Although items which are to be passed on to patients may not be given out from exhibition stands, they may be exhibited and demonstrated on stands and requests for them accepted for later delivery.

Patient support items may be provided to health professionals by representatives during the course of a promotional call and representatives may deliver such items when they are requested by health professionals, for example on reply paid cards.

Examples of items which might be acceptable include a peak flow meter as part of a scheme for patients to regularly record readings or a pedometer as part of a scheme to encourage exercise, perhaps for obese patients.

Provided that they have been appropriately documented and certified in advance as required by Clause 14.3, in limited circumstances patient support items may be made available for the use of health professionals even though they are not to be passed on to patients for them to keep. This is where their purpose is to allow patients to gain experience in using their medicines whilst under the supervision of a health professional. Examples include inhalation devices (with no active ingredient) and devices intended to assist patients to learn how to self-inject.

An 'inexpensive' item means one that has cost the donor company no more than £6, excluding VAT. The perceived value to the health professional and the patient must be similar.

Clause 18.2 Items Given to Patients

Items which may be made available to patients, for example by completing a request card enclosed with a medicine, 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 26.

No item for use by patients must be given for the purpose of encouraging patients to request a particular medicine.

Companies cannot run or sponsor competitions or quizzes for patients if prizes are offered to individuals. A competition for patients where the prizes were health related and were given to a clinic or similar might be acceptable.

Clause 18.3 Notebooks, Pens and Pencils

Notebooks, pens and pencils are the only items that can be provided to health professionals and other relevant decision makers for them to keep and then only at bona fide meetings.

They cannot be provided, for example, by representatives when calling upon health professionals. No individual attendee should receive more than one notebook and one pen or pencil.

The total cost to the donor company of all such items provided to an individual person attending a meeting must not exceed £6, excluding VAT. The perceived value to the recipient must be similar.

Notebooks, pens and pencils must not be given out from exhibition stands.

Notebooks, pens and pencils provided at company organised meetings may bear the name of the donor company but not the name of any medicine or any information about medicines.

Notebooks, pens and pencils included in conference bags at third party organised meetings may not bear the names of the donor companies or the name of any medicine or any information about medicines.

Clause 19

Medical and Educational Goods and Services

19.1 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. They must not be provided to individuals for their personal benefit. Medical and educational goods and services must not bear the name of any medicine but may bear the name of the company providing them.

19.2 The provision of medical and educational goods and services in the form of donations, grants and benefits in kind to institutions, organisations or associations that are comprised of health professionals and/or that provide healthcare or conduct research are only allowed if:

- they comply with Clause 19.1 or are made for the purpose of supporting research
- they are documented and kept on record by the company
- they do not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine
- details are publicly disclosed as donations, grants or benefits in kind or as research and development transfers of value.

Clause 19 Supplementary Information

Clause 19.1 Medical and Educational Goods and Services

Clauses 18.1 and 19.1 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. They must not be provided to individuals for their personal benefit.

The requirement in Clause 19.1 that medical and educational goods must not bear the name of any medicine does not apply where the goods involved consist of independently produced textbooks or journals which include as part of their texts the names of medicines.

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 other relevant decision makers 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 19.1 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.

If, during a promotional visit by a representative, a change in medication to one of the company's products is agreed, the representative may not then offer a therapy review service to facilitate the change as this would be seen as a way for the company to ensure that the agreed change would in fact be made.

(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 - Standards of conduct, performance and ethics for nurses and midwives.

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 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 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 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 NHS or other 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 relevant organisation would normally be expected to provide.

Clause 19.1 Switch and Therapy Review Programmes

Clauses 18.1 and 19.1 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 must enhance patient care, or benefit the NHS and maintain patient care, and must otherwise be in accordance with Clause 19.1 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 Disclosure

Transfers of value in relation to medical or educational goods and services must be publicly disclosed in relation to transfers

of value made in 2015 and each calendar year thereafter, giving in each case the financial amount or value and the name of the recipient.

Disclosure must be carried out in accordance with Clause 24.

Clause 19.2 Donations, Grants and Benefits in Kind

Donations and grants to individual health professionals are not covered by this clause. Company sponsorship of health professionals to attend events is covered by Clause 22.

Details of each grant, donation or benefit in kind (transfer of value) must be publicly disclosed, giving in each case the financial amount or value and the name of the recipient institution, organisation or association. Companies are also

encouraged to ask recipients to make such funding public.

Fees and agreed expenses should be disclosed separately.

The information required by Clause 19.2 must be publicly disclosed in respect of donations, grants and benefits in kind made in 2015 and each calendar year thereafter.

Disclosure must be carried out in accordance with Clause 24.

Disclosure for Calendar Years 2013 and 2014

For disclosures in relation to donations and grants made in calendar years 2013 and 2014, the requirements and procedures in Clause 18.6 and its supplementary information in the Second 2012 Edition of the Code continue to apply.

Clause 20

Joint Working

Joint working between one or more pharmaceutical companies and the NHS and others is acceptable provided that this is carried out in a manner compatible with the Code. Joint working must always benefit patients.

A formal written agreement must be in place and an executive summary of the joint working agreement must be made publicly available before arrangements are implemented.

Transfers of value made by companies in connection with joint working must be publicly disclosed.

Clause 20 Supplementary Information

Clause 20 Joint Working

The Department of Health defines joint working between the NHS and the pharmaceutical industry as situations where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery.

Each party must make a significant contribution and the outcomes must be measured. Treatments must be in line with nationally accepted clinical guidance where such exists. Joint working between the pharmaceutical industry and the NHS must be conducted in an open and transparent manner. Joint working must be for the benefit of patients but it is expected that the arrangements will also benefit the NHS and the pharmaceutical company or companies involved. Joint working differs from the situation where pharmaceutical companies simply provide funds for a specific event or programme.

The Department of Health has issued Best practice guidance on joint working between the NHS and pharmaceutical industry and other relevant commercial organisations. The Department of Health and the ABPI have jointly issued Moving beyond sponsorship: interactive toolkit for joint working between the NHS and the pharmaceutical industry.

The ABPI has produced guidance notes on joint working between pharmaceutical companies and the NHS and others for

the benefit of patients. The ABPI Guidance refers to the requirements of the Code but goes well beyond them.

When considering joint working, companies should take account of the guidance which has been issued by the ABPI and the Department of Health. Joint working is acceptable in principle provided that it is carried out in conformity with the Code. In particular, it must not constitute an inducement to health professionals or other relevant decision makers to prescribe, supply, recommend, buy or sell any medicine. It must therefore always be ensured that any and all of the benefits of joint working which are due to the NHS, go not to individuals or practices but to an NHS or other organisation.

A joint working agreement can be based on the use of a particular medicine of a company party to the agreement, but only if the requirements below are complied with and only if the parties have satisfied themselves that the use of the medicine will enhance patient care. Goods and services provided by the company as part of the joint working agreement must be relevant to the medicines involved and the agreement as a whole must be fair and reasonable. Any goods and services provided by the company must themselves contribute to patient care.

The written agreement must cover the following points:

- the name of the joint working project, the parties to the agreement, the date and the term of the agreement
- the expected benefits for patients, the NHS and the pharmaceutical company; patient benefits should always be stated first and patient outcomes should be measured
- an outline of the financial arrangements
- the roles and responsibilities of the NHS and the pharmaceutical company and how the success of the project will be measured, when and by whom; all aspects of input should be included
- the planned publication of any data or outcomes
- if a pharmaceutical company enters into a joint working agreement on the basis that its product is already included in an appropriate place on the local formulary, a clear reference to this should be included in the joint working agreement so that all the parties are clear as to what has been agreed
- contingency arrangements to cover possible unforeseen circumstances such as changes to summaries of product characteristics and updated clinical guidance; agreements should include a dispute resolution clause and disengagement/exit criteria including an acknowledgement by the parties that the project might need to be amended or stopped if a breach of the Code is ruled

- publication by the company of an executive summary of the joint working agreement, for example on a clearly defined website or section of a website, such as on the company's or companies' website; the NHS organisation should also be encouraged to publish this.

The requirement to make the executive summary public applies to joint working projects started on or after 1 May 2011 or ongoing on that date.

Attention is drawn to the certification requirements set out in Clause 14.3 which apply to material relating to joint working including the joint working agreement, the project initiation documentation and the executive summary of the joint working agreement. Only the final documents etc for any joint working project need be certified. All documents etc used during the development of the project should be of the same standard as certified material but there is no requirement to certify such materials.

Clause 19.2 is relevant to a joint working agreement between a pharmaceutical company and the NHS which does not involve the use and purchase of any of the company's medicines.

Although the ABPI Guidance is aimed principally at joint working between pharmaceutical companies and the NHS, it

also covers joint working conducted through third party service providers and/or with suppliers of private healthcare.

More detail as to the requirements for joint working is provided in the ABPI Guidance which should be consulted when joint working is contemplated.

Joint working should be distinguished from straightforward sales where medicines are simply sold and there are no accompanying goods and services etc and from package deals and outcome or risk sharing agreements as defined in the supplementary information to Clause 18.1.

Clause 20 Disclosure

The information required by Clause 20 as to transfers of value must be publicly disclosed in relation to transfers of value made in 2015 and each calendar year thereafter, giving in each case the financial amount or value and the name of the recipient.

Companies must ensure that the amount spent on joint working projects is made public irrespective of whether the value is transferred to a healthcare organisation or some other funding model is used.

Disclosure must be carried out in accordance with Clause 24.

Clause 21

Relationships and Contracts with Certain Organisations

Contracts between companies and institutions, organisations or associations of health professionals under which such institutions, organisations or associations provide any type of services on behalf of companies (or any other type of funding by the company not otherwise covered by the Code) are only allowed if such services (or other funding):

- comply with Clause 19.1 or are provided for the purpose of supporting research
- do not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

Clause 22

Meetings, Hospitality and Sponsorship

22.1 Companies must not provide hospitality to members of the health professions and other relevant decision makers except in association with scientific meetings, promotional meetings, scientific congresses and other such meetings, and training. 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 other relevant decision makers.

Pharmaceutical companies must publicly disclose details of transfers of value made to such institutions, organisations or associations.

Clause 21 Supplementary Information

Clause 21 Disclosure

The information required by Clause 21 must be publicly disclosed in relation to transfers of value made in 2015 and each calendar year thereafter, giving in each case the financial amount or value and the name of the recipient institution, organisation or association.

Fees and agreed expenses should be disclosed separately.

Disclosure must be carried out in accordance with Clause 24.

22.2 The cost of a meal (including drinks) provided by way of subsistence must not exceed £75 per person, excluding VAT and gratuities.

22.3 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.

22.4 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.

22.5 Pharmaceutical companies must publicly disclose financial details of sponsorship of UK health professionals and other relevant decision makers in relation to attendance at meetings. Sponsorship in this context includes registration fees and the costs of accommodation and travel, both inside and outside the UK.

Clause 22 Supplementary Information

Clause 22.1 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 22.1 with regard to hospitality and venues.

Companies should only offer or provide economy air travel to delegates sponsored to attend meetings. Delegates may organise and pay at their own expense the genuine cost of an upgrade. For flights that are scheduled to take longer than six hours companies may pay for an upgrade from economy to premium economy or similar.

Pharmaceutical companies may appropriately hold or 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, advisory board meetings, visits to research and manufacturing facilities, planning, training and investigator meetings for clinical trials and non-interventional studies, launch meetings for new products, management training courses, patient support group meetings and 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, extravagant or deluxe venues must not be used, companies must not sponsor or organise entertainment (such as sporting or leisure events) 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
- any hospitality provided must not extend to a spouse or other such person unless that person is a health professional or other relevant decision maker 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 other relevant decision makers etc. 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.

Promotional material which is displayed or provided at international meetings held outside the UK may, unless prohibited or otherwise regulated by local laws and regulations, refer to medicines or their indications which are not registered in the country where the event takes place, or which are registered under different conditions, so long as any such material is accompanied by a suitable statement indicating countries where the product is registered and making clear that the product is not registered locally. Any such promotional material which refers to the prescribing information authorized in a country or countries where the medicine is registered must be accompanied by an explanatory statement indicating that registration conditions differ internationally.

The requirements relating to international meetings held in the UK are set out in the supplementary information to Clause 3.

The requirements of the Code do not apply to the provision of hospitality other than to that referred to in Clauses 22.1 and 27.2 and the supplementary information to Clauses 23 and 26.2.

Clause 22.1 Meetings Organised by Affiliates Outside the UK

Companies should remind their affiliates outside the UK that the ABPI Code of Practice must be complied with if UK health professionals attend meetings which they organise regardless of whether such meetings occur in the UK or abroad.

Clause 22.1 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.

Clause 22.1 Health Professionals' Codes of Conduct

The General Medical Council is the regulatory body for doctors and is responsible for giving guidance on standards of professional conduct and on medical ethics. In its guidance,

the GMC advises that 'You must not allow any interests you may have to affect the way you prescribe for, treat, refer or commission services for patients' and 'You must not ask for or accept – from patients, colleagues or others – any inducement, gift or hospitality that may affect or be seen to affect the way you prescribe for, treat or refer patients or commission services for patients. You must not offer these inducements'.

The General Pharmaceutical Council is the regulatory body for pharmacists and pharmacy technicians. The Council's Standards of conduct, ethics and performance state 'Do not ask for or accept gifts, rewards or hospitality that may affect, or be seen to affect, your professional judgement'.

The Code of the Nursing & Midwifery Council, Standards of conduct, performance and ethics for nurses and midwives, states 'You must not abuse your privileged position for your own ends' and 'You must ensure that your professional judgement is not influenced by any commercial considerations'.

Clause 22.1 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. 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 22.2 Maximum Cost of a Meal

The maximum of £75 plus VAT and gratuities is appropriate only in very exceptional circumstances, such as a dinner at a residential meeting for senior consultants or a dinner at a learned society conference with substantial educational content. The cost of a meal (including drinks) should normally be well below this figure. The requirements relating to hospitality in Clause 22.1 and its supplementary information still apply.

The maximum of £75 plus VAT and gratuities (or local equivalent) does not apply when a meeting is held outside the UK in a European country where the national association is a member of EFPIA and thus covered by EFPIA Codes. In such circumstances the limits in the host country code would apply. Information can be found at www.EFPIA.eu.

Clause 22.3 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 22.4 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 22.5 Sponsorship of Attendance

Disclosure of this information must be carried out in accordance with Clause 24.

Meetings at which attendance is sponsored by companies must also comply with Clause 22.1.

The information required by Clause 22.5 must be publicly disclosed in respect of sponsorship for attendance at meetings held in 2015 and each calendar year thereafter.

The information which must be disclosed comprises registration fees and the costs of accommodation and travel, both inside and outside the UK. The name of each recipient and the cost of the sponsorship of that recipient must be given.

Where a transfer of value is made to a health professional indirectly via a healthcare organisation such a transfer should be disclosed once only, preferably as being a transfer to the health professional.

Disclosure for Calendar Years 2013 and 2014

For disclosures in relation to calendar years 2013 and 2014, the requirements and procedures in Clause 19.4 and its supplementary information in the Second 2012 Edition of the Code still apply.

Clause 23

The Use of Consultants

23.1 Health professionals and other relevant decision makers may be used as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or travel. The arrangements which cover these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

- a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services
- a legitimate need for the services must be clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants
- the criteria for selecting consultants must be directly related to the identified need and the persons responsible for selecting the consultants must have the expertise necessary to evaluate whether the particular consultants meet those criteria

- the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need
- the contracting company must maintain records concerning, and make appropriate use of, the services provided by consultants
- the hiring of the consultant to provide the relevant service must not be an inducement to prescribe, supply, administer, recommend, buy or sell any medicine
- the compensation for the services must be reasonable and reflect the fair market value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensating health professionals and other relevant decision makers
- in their written contracts or agreements with consultants, companies must include provisions regarding the obligation of the consultant to declare that he/she is a consultant to the company whenever he/she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company. Similarly, companies that employ, on a part-time basis, health professionals that

are still practising their profession must ensure that such persons are obliged to declare their employment arrangement with the company whenever they write or speak in public about a matter that is the subject of the employment or any other issue relating to that company.

23.2 Pharmaceutical companies must publicly disclose details of the fees paid to consultants in the UK, or to their employers on their behalf, for certain services rendered by them such as chairing and speaking at meetings, assistance with training and participation in advisory boards etc. It includes payments to consultants in relation to research and development work, including the conduct of clinical trials.

23.3 In addition to the information required to be made public by Clause 23.2, companies must publicly disclose details of payments made to consultants in relation to market research (unless the company concerned is not aware of the identities of those participating in the market research).

23.4 Fees, expenses and the like due to consultants in relation to Clauses 23.2 and 23.3 must be disclosed whether paid directly to them or to their employers or to healthcare organisations or to companies or charities etc.

Clause 23 Supplementary Information

Clause 23 The Use of Consultants

The term 'consultant' in Clause 23 covers any health professional or other relevant decision maker consulted for the purposes described in Clause 23 regardless of their normal roles.

Other relevant decision makers covered by Clause 23 are those who could influence in any way the prescription, supply, administration, recommendation, purchase or sale of any medicine.

Clause 23 Patient Organisations

The provision of services to pharmaceutical companies by patient organisations is covered by Clause 27.8.

Clause 23.1 The Use of Consultants

The requirement that contracts or agreements with consultants must include provisions regarding their obligation to declare the arrangement whenever they write or speak in public applies to contracts entered into or renewed on or after 1 May 2011. Companies are encouraged to renegotiate existing contracts to include such provisions at their earliest convenience.

Limited market research, such as one-off telephone interviews or mail/email/Internet questionnaires was excluded from the scope of Clause 20.1 of the 2012 Code, provided that the consultant was not consulted in a recurring manner (either with respect to the frequency of the calls generally or of calls relating to the same research) and that the remuneration was minimal. Following implementation of Clause 20.3 of the 2012 Code, payments made in relation to this limited market research must be made publicly available in accordance with that clause.

If health professionals or other relevant decision makers attend events in a consultant or advisory capacity the relevant provisions of Clause 22 apply.

Clause 23.2 Disclosure

The information required by Clause 23.2 must be publicly disclosed in respect of the calendar year 2015 and each calendar year thereafter.

Disclosure must be carried out in accordance with Clause 24.

The information which must be disclosed is the total amount paid in a calendar year to each consultant who has provided services. Companies may, of course, give greater detail, for example by giving separate figures for different categories of service.

Fees and agreed expenses should be disclosed separately.

The names of the consultants must be disclosed except in relation to payments in relation to research and development work, including clinical trials, as defined below, where disclosure should be on an aggregate basis.

Clause 23.2 Research and Development Transfers of Value

For the purpose of disclosure research and development transfers of value are transfers of value to health professionals or healthcare organisations related to the planning or conduct of:

- non-clinical studies (as defined in the OECD Principles of Good Laboratory Practice)
- clinical trials (as defined in Directive 2001/20/EC)
- non-interventional studies that are prospective in nature and involve the collection of data from, or on behalf of, individual or groups of health professionals specifically for the study.

Costs that are subsidiary to these activities can be included in the aggregate amount.

Clause 23.3 Disclosure

Clause 23.3 relates only to market research using consultants where the pharmaceutical company knows the identity of the

consultants. This is because the focus of the requirements concerning transparency is on areas where there are direct relationships between the parties and that is not so where the company does not know the identity of the participants.

Clause 24

Transfers of Value to Health Professionals and Healthcare Organisations

24.1 Companies must document and publicly disclose certain transfers of value made directly or indirectly to health professionals and healthcare organisations located in Europe.

24.2 The transfers of value covered by Clause 24.1 are:

- joint working in accordance with Clause 20
- donations, grants and benefits in kind provided to institutions, organisations and associations in accordance with Clauses 19.1 and 19.2
- contracts between companies and institutions, organisations and associations in accordance with Clause 21
- sponsorship of attendance by health professionals and other relevant decision makers at meetings in accordance with Clause 22.5
- fees and expenses paid to health professionals and other relevant decision makers, or to their employers on their behalf, in accordance with Clauses 23.2, 23.3 and 23.4
- contributions towards the costs of meetings paid to healthcare organisations or to third parties managing events on their behalf, which may include sponsorship of health professionals by way of registration fees and accommodation and travel.

24.3 Clause 24.1 does not apply to transfers of value to patient organisations. These transfers of value are covered by Clauses 27.7 and 27.8.

24.4 Disclosures must be made annually in respect of each calendar year. Disclosure must be in the first six months after the end of the calendar year in which the transfers of value were made.

Clause 24 Supplementary Information

Clause 24.1 Transfers of Value

The term 'transfer of value' is defined in Clause 1.10.

The term 'Europe' comprises those countries that are within the EU and other countries with a trade association that is a member of EFPIA.

The term 'health professional' in relation to disclosure of transfers of value also includes any employee of a pharmaceutical company whose primary occupation is that of a practising health professional as defined in Clause 1.4.

Disclosure for Calendar Years 2013 and 2014

For disclosures in relation to the calendar years 2013 and 2014, the requirements and procedures in Clauses 20.2 and 20.3 and their supplementary information in the Second 2012 Edition of the Code still apply.

24.5 The information disclosed must remain in the public domain for at least three years from the time of disclosure.

24.6 Companies must document all disclosures and retain the records for at least five years after the end of the calendar year to which they relate.

24.7 Different categories of transfers of value to individual health professionals can be aggregated on a category by category basis, provided that itemised disclosure would be made available upon request to the relevant recipient or the relevant authorities.

Payments to healthcare organisations are required to be disclosed on a per activity basis.

24.8 Where a transfer of value is made to a health professional indirectly via a healthcare organisation such a transfer should be disclosed once only, preferably as being a transfer to the health professional.

24.9 Where recipients of transfers of value cannot be identified for legal reasons, the amount attributable to such transfers must be disclosed on an aggregate basis. The number of recipients involved must be stated together with the percentage of all recipients that they represent and the aggregate amount attributable to transfers of value to such recipients.

24.10 Each company providing transfers of value must publish a note summarising the methodologies used by it in preparing the disclosures and identifying each category of transfer of value. The note, including a general summary and/or country specific considerations, must describe the recognition methodologies applied and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues relating to the timing and amount of transfers of value for the purposes of this Code.

Disclosure is required even if the payments etc are made by overseas affiliates, head offices in the UK or overseas and UK based offices.

Clause 24.1 Consent to Disclosure

Companies are encouraged to include in a contract involving a transfer of value provisions regarding the consent of the recipient to its disclosure. In addition, companies are encouraged to renegotiate existing contracts at their earliest convenience to include such consent to disclosure. Companies must ensure that they have appropriate arrangements in place to lawfully disclose information about transfers of value.

Clause 24.1 Mode of Disclosure

There will be a central platform for disclosure in the UK which companies must use. The template to be used is available from the Authority's website www.pmcpa.org.uk.

Clause 24.1 Date of Implementation

The information required by Clause 24.1 must be disclosed in respect of transfers of value made in 2015 and each calendar year thereafter.

The disclosure of information about certain transfers of value was a requirement of the Second 2012 Edition of the Code and

its immediate predecessors. The provisions in the Second 2012 Edition of the Code (Clauses 18.6, 19.4, 20.2 and 20.3) continue to apply in relation to transfers of value made in calendar years prior to 2015.

Clause 24.2 Further Information

The clauses of the Code noted in Clause 24.2 should be consulted for further information about the requirements. In addition, the requirements of Clauses 22.1 and 22.5 should be borne in mind in relation to sponsorship of meetings.

Clause 25

Scientific Services

25.1 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.

25.2 Companies must also have a scientific service to deal with the approval and supervision of non-interventional studies. This scientific service must include a registered medical practitioner or a pharmacist registered in the UK, who will be responsible for the oversight of non-interventional studies (including the review of any responsibilities relating to such studies, particularly those

given to medical representatives). That person must state in writing that he or she has examined the protocol relating to the non-interventional study and that in his or her belief it is in accordance with the requirements of the Code.

Clause 25 Supplementary Information

Clauses 25.1 and 25.2 Scientific Services

Companies are free to decide whether there is one scientific service in charge of both responsibilities or separate services with clearly delineated duties.

Clause 14 does not apply to the examination of non-interventional studies.

Clause 26

Relations with the Public and the Media

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

26.2 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.

26.3 Any material which relates to a medicine and which is intended for patients taking that medicine must include the statement below or a similar one:

'Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also

report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.'

When the material relates to a medicine which is subject to additional monitoring an inverted black equilateral triangle must be included on it together with the statement below or a similar one:

'This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See www.mhra.gov.uk/yellowcard for how to report side effects.'

26.4 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.

26.5 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.

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

Clause 26 Supplementary Information

Clause 26.1 Advertising of Medicines to the Public

The advertising of prescription only medicines to the public is also prohibited by the relevant regulations relating to advertising.

The promotion of medicines to the public for self medication purposes is covered by the Consumer Code of the Proprietary Association of Great Britain (PAGB).

Clause 26.2 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 26.1. The provisions of Clause 26.4 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. Companies should take particular care if they use social media.

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 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 Care 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 material concerning a medicine with a view to its provision to patients to whom the medicine has already been prescribed. Such material must be factual and non-promotional and clearly state the intended audience.

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 22.

Items for patients or for use by patients are covered in Clause 18.2. and its supplementary information.

Clause 26.2 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 26.2 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 26.2 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 26.2 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, AWMMSG or SMC, provided the information is accurate, not misleading, not promotional in nature and otherwise complies with Clause 26.2.

Clause 26.3 Obligatory Wording

The obligatory wording required corresponds to that required for package leaflets by the European Quality Review of Documents Group which updated the requirements in The Human Medicines Regulations 2012. If the suggested wording is not used the same meaning must be conveyed.

In the event that the website address given in Clause 26.3 is changed by the Medicines and Healthcare Products Regulatory Agency, companies may use a statement incorporating the new address as soon as the change is made and must use the new address within one year of the change.

Clause 26.3 Black Triangle Symbol

Details of the black triangle symbol can be found in the supplementary information to Clause 4.11.

Clause 26.4 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 26.1 and 26.2 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 adverse reactions, 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 Choices, NHS 111, their equivalents in the devolved nations 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 27

Relationships with Patient Organisations

27.1 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.

Companies must respect the independence of patient organisations.

27.2 When working with patient organisations, companies 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 27.9) and the prohibition on advertising prescription only medicines to the public (Clause 26.1). The requirements of Clause 22, which covers meetings for health professionals and other relevant decision makers, also apply to pharmaceutical companies supporting patient organisation meetings.

27.3 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.

27.4 No company may require that it be the sole funder of a patient organisation or any of its programmes.

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

27.6 A company must not seek to influence the text of patient organisation material in a manner favourable to its own commercial interests. This does not preclude a company from correcting factual inaccuracies.

27.7 Each company must make publicly available, at a national or European level, a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support, which must include a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the significance of the support. The list of organisations being given support must be updated at least once a year.

The published information must include the monetary value of financial support and of invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value, the published information must describe clearly the non-monetary value that the organisation receives.

27.8 Contracts between companies and patient organisations under which they provide any type of services to companies are only allowed if such services are provided for the purpose of supporting healthcare or research.

Patient organisations may be engaged as experts and advisors for services such as participation at advisory board meetings and speaker services. The arrangements that cover consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

- a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services
- a legitimate need for the services must be clearly identified and documented in advance of requesting the services and entering into the arrangements
- the criteria for selecting services must be directly related to the identified need and the persons responsible for selecting the service must have the expertise necessary to evaluate whether the particular experts and advisors meet those criteria
- the extent of the service must not be greater than is reasonably necessary to achieve the identified need
- the contracting company must maintain records concerning, and make appropriate use of, the services

- the engaging of patient organisations must not be an inducement to recommend a particular medicine
- the compensation for the services must be reasonable and not exceed the fair market value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensating patient organisations
- in their written contracts with patient organisations, companies are strongly encouraged to include provisions regarding an obligation of the patient organisation to declare that they have provided paid services to the company whenever those concerned write or speak in public about a matter that is the subject of the agreement or any other issue relating to that company
- each company must make publicly available, at a national or European level, a list of patient organisations that it has engaged to provide significant contracted services, which must include a description of the nature of the services provided that is sufficiently complete to enable the average reader to form an understanding of the arrangement without the necessity to divulge confidential information. Companies must also make publicly available the total amount paid per patient organisation over the reporting period. The list of organisations engaged must be updated at least once a year.

27.9 Companies must ensure that their sponsorship is always clearly acknowledged from the outset. The wording of the declaration of sponsorship must accurately reflect the nature of the company's involvement.

Clause 27 Supplementary Information

Clause 27.1 Other Codes and Guidelines

There are other codes and guidelines which cover patient groups, including Charity Commission requirements.

Clause 27.2 Purpose of Materials and Activities

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 27.2 Hospitality for Carers

Although the requirements in Clause 22 relating to the provision of hospitality at meetings apply where pharmaceutical companies support patient organisation meetings and their representatives, in exceptional circumstances, in the case of clear health needs such as disability, companies can pay for subsistence, accommodation, genuine registration fees and reasonable travel costs for an accompanying carer.

Clause 27.3 Written Agreements

The written agreement must include:

- the name of the activity

- the names of the organisations involved (pharmaceutical company, patient organisations and any third parties which will be brought in to help)
- the type of activity (eg unrestricted grant, specific meeting or publication etc)
- the objectives
- the respective roles of the company and the patient organisation
- the time-frame
- the amount of funding
- a description of significant indirect/non-financial support (eg the donation of public relations agency time or free training courses)
- a statement that all parties are fully aware that sponsorship must be clearly acknowledged and apparent from the start
- the code or codes of practice which will apply
- the signatories to the agreement
- the date of the agreement.

Attention is drawn to the certification requirements as set out in Clause 14.3.

Clause 27.5 Use of Patient Organisation Logos or Material

Even with the organisation's permission the use of its logo or material must not be such as to otherwise breach the Code.

Clause 27.7 Further Information

An indication of the patient organisation's total income and/or the company's support as a percentage of the patient organisation's total income may be given. Neither is obligatory.

Companies are encouraged to be prepared to make available up-to-date information about such activities at any time in response to enquiries.

Clauses 27.7 and 27.8 Transfers of Value to Patient Organisations

Transfers of value to patient organisations made in accordance with Clauses 27.7 and 27.8 are not subject to the requirements relating to transfers of value set out in Clause 24. Clause 24.3 excludes them from its scope.

Clause 28

The Internet

28.1 Promotional material about prescription only medicines directed to a UK audience which is provided on the Internet must comply with all relevant requirements of the Code.

28.2 Information or promotional material about medicines covered by Clause 28.1 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.

28.3 Information about medicines covered by Clauses 28.1 and 28.2 which is provided on the Internet and which is intended for members of the public must comply with Clause 26.2.

28.4 A medicine covered by Clause 28.1 may be advertised in a relevant independently produced electronic journal intended for health professionals or other relevant decision makers which can be accessed by members of the public.

28.5 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.

28.6 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 28 Supplementary Information

Clause 28.1 Access

Unless access to promotional material about prescription only medicines is limited to health professionals and other relevant decision makers, 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 28.4 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 28.5 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 package 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 28.5 Information on Clinical Trials

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

Attention is drawn to Clause 13.1 and its supplementary information.

Clause 28.6 Sites Linked via Company Sites

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

Clause 29

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.

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 2015.

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 as well as for the complaints procedure. It is also responsible for arranging for conciliation between companies when requested to do so and for arranging for the scrutiny of advertising and meetings on a regular basis.

The Authority is not an investigatory body as such. It asks the respondent company for a complete response and may ask the parties to a case for further information in order to clarify the issues. It is essentially an adversarial process in which the evidence to be taken into account comes from the complainant and the respondent company, though the Authority can seek evidence from third parties where necessary. A complainant has the burden of proving their complaint on the balance of probabilities. The system is designed so that both parties can participate fully in the process. Although anonymous complaints are accepted, it is preferable if complainants from outside the industry provide a name, contact details and relevant information about their interests in the matter of complaint. 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.

All complaints are judged on the evidence provided by the parties. The weight to be attached to any evidence may be adversely affected if the source is anonymous and thus in some instances it will not be possible for such a complaint to proceed.

Complaints made under the Code 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.

Complaints should be submitted to the Director of the Prescription Medicines Code of Practice Authority, 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT, telephone 020-7747 8880, facsimile 020-7747 8881, email complaints@pmcpa.org.uk.

STRUCTURE AND RESPONSIBILITIES

1 Prescription Medicines Code of Practice Authority

1.1 The Prescription Medicines Code of Practice Authority (the 'Authority') is responsible for the administration of the Code of Practice for the Pharmaceutical Industry (the 'Code') 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 arranging for the scrutiny of 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 (the 'Panel') and, where required, by the Code of Practice Appeal Board (the '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) (the 'ABPI Board') and consists of the Director, Deputy Director, Secretary and Deputy Secretary.

Notwithstanding the above, 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 Deputy Director is authorized to act on his behalf. In the absence of the Director and Deputy Director, the Secretary is authorized to act on the Director's behalf.

- 1.4 To facilitate the complaints procedure by ensuring that the requisite information is available, the Director may 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 Director may consult the Appeal Board upon any matter concerning the Code or its administration.

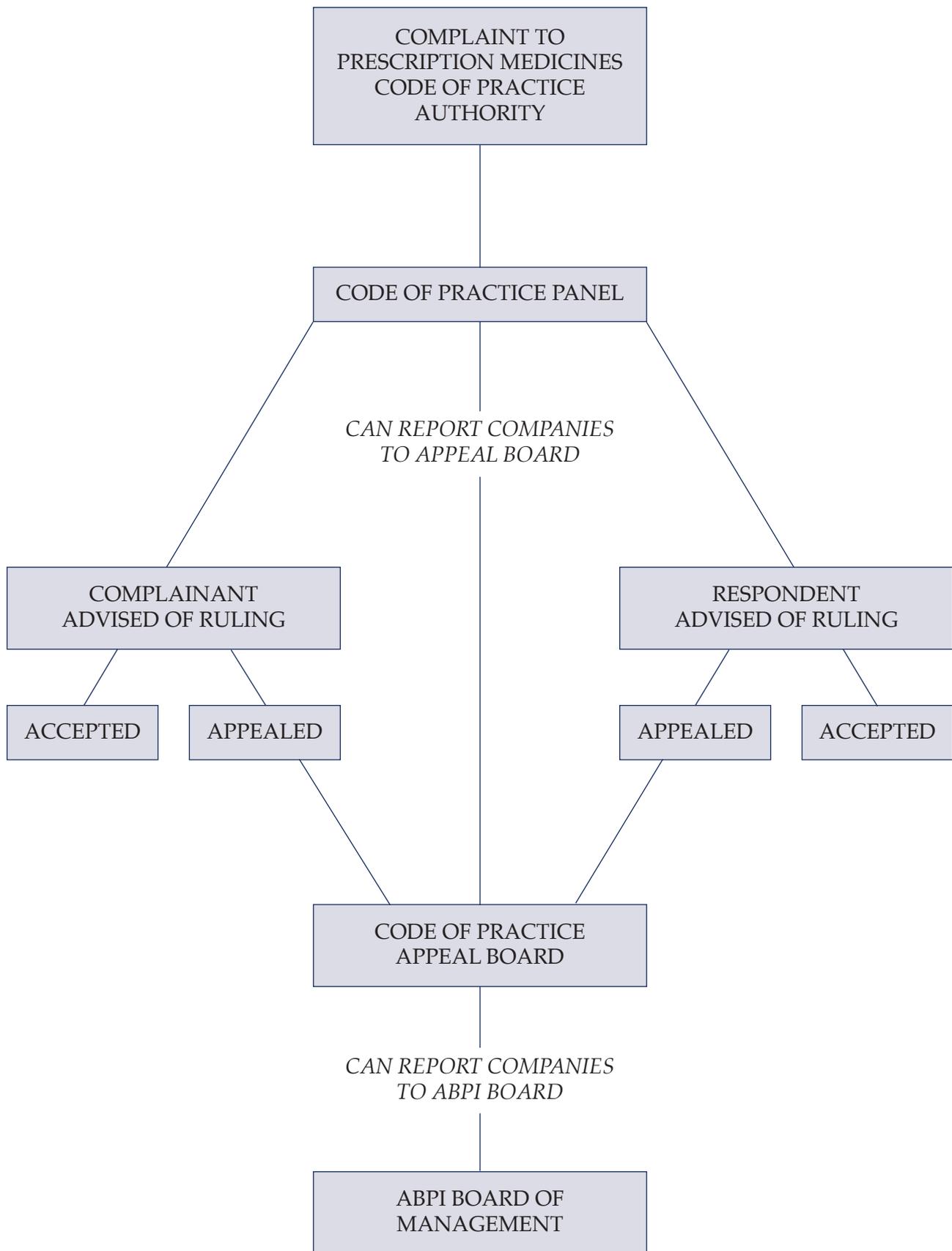
2 Code of Practice Panel – Constitution and Procedure

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

The member of the Authority who acted as case preparation manager for a particular case must not participate when the Panel considers it or be present when it does so.

The parties have no right to appear or be represented before the Panel.

- 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 Deputy Director or, in his absence, the Secretary, acts as Chairman of the Panel and has both an original and a casting vote.



Rulings are made on the basis that a complainant has the burden of proving their complaint on the balance of probabilities.

- 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 Vacancies for independent members of the Appeal Board, including the Chairman, are advertised in appropriate journals and/or the national press.

The Appeal Board and its Chairman are appointed by the ABPI Board. The appointment of independent members to the Appeal Board, including the Chairman, is made following consultation with the Medicines and Healthcare Products Regulatory Agency.

- 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 treating patients
- one independent registered pharmacist appointed following consultation with the Royal Pharmaceutical Society.
- 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 lay member
- four registered medical practitioners who are medical directors or senior executives of pharmaceutical companies
- four 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 including the provision of case papers.

The Director, Deputy Director, Secretary and Deputy Secretary of the Authority may be present as observers 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 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. Four of those present, in addition to the Chairman, must be independent members, at least one of whom must be a registered medical practitioner, and there must also be present three members from pharmaceutical companies, at least one of whom must be a registered medical practitioner.

For the consideration of any particular case, or a report under Paragraph 11 below, independent members, including the Chairman, must be in a majority.

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. No one may be co-opted in relation to any case in which he has acted as a referee in accordance with Paragraphs 5.1, 5.2, 5.3, 7.2, 7.4, 7.5 and 7.6 below.

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

Rulings are made on the basis that a complainant has the burden of proving their complaint on the balance of probabilities.

- 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.

The complainant and the respondent are advised in advance of the membership of the Appeal Board, including potential co-optees, and asked if they have any objections to particular members and the grounds for such objections. Any member in respect of whom there are valid objections must withdraw from the Appeal Board during consideration of the case. The Chairman determines whether objections are valid.

Members of the Appeal Board must declare any other interest in a case prior to its consideration. Having consulted the representatives of the parties (if present), the Chairman determines whether it is appropriate for a particular 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 Director must assign a member of the Authority (who may be the Director) to be the case preparation manager to process the

matter and, if appropriate, prepare case papers for the Panel.

The case preparation manager must not divulge to other members of the Authority details of matters being processed until the formal case papers are provided to the Panel for consideration as provided for in Paragraph 5.5 below.

The Director is responsible for ensuring that the preparation of a case and the adjudication of it are carried out by different members of the Authority and must take steps to make certain that this separation is maintained in the event of absences of those involved.

The Director may delegate to a case preparation manager one or more of his responsibilities under this Constitution and Procedure when he considers it appropriate and necessary to do so.

The case preparation manager:

- determines whether a case should go before the Panel
- may invite evidence from third parties when considered to be appropriate even though the primary responsibility for the provision of evidence lies with the parties to a case
- may delay processing a complaint if the facts are essentially similar to those before an external forum, such as an employment tribunal; this does not apply to matters before the Medicines and Healthcare Products Regulatory Agency
- may amalgamate a complaint with an ongoing complaint or complaints where two or more complaints are based on essentially the same evidence.

When a complaint is delayed or amalgamated, as above, the complainant may appeal against the delay or amalgamation to an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination which is final.

- 5.2 The managing director or chief executive or equivalent of the company concerned is requested to provide a complete response to the matters of complaint.

To assist companies in ensuring that a complete response is submitted the case preparation manager may suggest relevant supporting material to be supplied. It is nonetheless the responsibility of the respondent to ensure that a full response is submitted. If the complainant is not a pharmaceutical company the case preparation manager may suggest the clauses of the Code to be addressed.

If a complaint is received about a company other than one of those referred to in Paragraph 5.1 above, it is invited by the case preparation manager 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 Medicines and Healthcare Products Regulatory Agency.

Unless the information is disclosed in the complaint, a complainant other than a pharmaceutical company is asked whether or not they have any commercial, financial or other interest in the matter of complaint or in the company concerned, such as whether the complainant is an employee or ex-employee, or in a competitor.

Such interests will be disclosed to the respondent company and will normally be included in the case report.

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 Panel where no breach of the Code was ruled and which was not the subject of appeal to the 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 an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination 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 will be so advised. If the complainant does not accept that view, the matter is referred to an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination which is final.

- 5.3 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. This requirement does not apply where the allegation is that a company has failed to comply with an undertaking that it has given and is in breach of Clause 29 of the Code.

If, in the view of the Director, that condition has not been met, the complainant shall be so advised. If the complainant does not accept that view, the matter is referred to an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination which is final.

Attention is drawn to the availability of conciliation prior to making a complaint as referred to in Paragraph 18.2 below. Information about conciliation is available from the Director.

- 5.4 Upon receipt of a complaint, the company concerned has ten working days in which to submit its comments in writing.
- 5.5 When the respondent company's response is received the case is referred to the Panel to determine whether or not there has been a breach of the Code.
- 5.6 When a company advises the Authority that it may have breached the Code, the Director will treat the matter as a complaint. The company's response is invited. The case preparation manager may suggest the clauses of the Code to be addressed. When the response is received the procedure under Paragraph 5.5 above will be followed.
- 5.7 The parties must be notified that a case has been referred to the Panel.

6 Complaints Arising from Media Criticism

- 6.1 When it appears to the Director from media reports (other than letters to the editor of a publication) that a company may have breached the Code, the matter is treated as a complaint.

The author of the article, or the editor where no author is named, is treated as the complainant.

The author, or editor, is asked if they want to be involved in the case and whether they have any additional information to submit. The consequences of not being involved (no right of appeal and no right to comment on a respondent's appeal or the proposed text of the case report) must be explained in writing. If the author or editor declines involvement, this is stated in the case report.

6.2 A published letter from which it appears that a company may have breached the Code is dealt with as a complaint with the author being treated as the complainant. The procedure set out in Paragraph 6.1 above will be followed.

7 Code of Practice Panel - Rulings

7.1 Where the 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 an

independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination 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.

Notice of appeal must be given within five working days of notification of the Panel's ruling and the appeal must be lodged within ten days of notification of the Panel's ruling.

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.

Relevant material previously submitted to the Panel is provided to the Appeal Board. All additional material which the complainant and the respondent company want the Appeal Board to consider must be submitted in writing with the appeal, with the respondent company's comments on the reasons given by the complainant for the appeal or with the complainant's comments on the respondent company's comments on the reasons given by the complainant for the appeal. No new material may be introduced when the appeal is heard by 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 an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, who will determine whether those particular comments can be included in the evidence which goes before the Appeal Board. The referee'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.

Relevant material previously submitted to the Panel is provided to the Appeal Board. All additional material which the complainant and the respondent company want the Appeal Board to consider must be submitted in writing with the appeal or with the complainant's comments on the reasons given by the respondent company for the appeal. No new material may be introduced when the appeal is heard by 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 an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, who will determine whether those particular details can be included in the evidence which goes before the Appeal Board. The referee'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 an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination which is final.

- 7.6 Where the Panel rules no breach of the Code because it considers the matter of complaint is not within the scope of the Code the complainant and the respondent company are so advised in writing.

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 an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination which is final.

The complainant may appeal against the Panel's ruling to an independent referee identified by the Director and the Chairman of the Appeal Board, for example a former independent member of the Appeal Board, for his determination which is final. An appeal must be accompanied by reasons as to why the Panel's ruling is not accepted. These reasons will be provided to the referee. The appeal must be lodged within ten working days of notification of the ruling of the Panel.

The respondent company has five working days to comment on the reasons given by the complainant for the appeal and these comments will be provided to the referee.

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 provided to the respondent company and the referee.

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 the referee must decide whether he can take those comments into consideration when making his determination.

In such an appeal, the referee must consider no more than whether or not the matter of complaint is within the scope of the Code.

If the referee determines that the matter is not within the scope of the Code the complainant and the respondent company are so advised in writing.

If the referee determines that the matter is within the scope of the Code the complainant and the respondent company are so advised in writing. The case is referred back to the Panel for it to be considered on its merits and the procedure in Paragraph 5.5 above will be followed.

No administrative charges apply in relation to proceedings under Paragraph 7.6 and there will be no case reports.

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 and 7 above will be reported to the Appeal Board.
- 8.2 The 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 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 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 relevant information as 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, it may require the company to take steps to recover items given in connection with the promotion of a medicine or non-promotional items provided to health professionals and members of the public and the like. Written details of the action taken must be provided to the Appeal Board.

10.4 Where the Appeal Board rules that there is a breach of the Code, it may require an audit of the company's procedures in relation to the Code to be carried out by the 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 it cannot approve such material. All of the costs of pre-vetting must be met by the company concerned.

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, it 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, it 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 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 procedure 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:

- reprimand the company and publish details of that reprimand
- require an audit of the company's procedures in relation to the Code to be carried out by the 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 it cannot approve such material; all of the costs of pre-vetting must be met by the company concerned

- 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
- require the company to take steps to recover items given in connection with the promotion of a medicine or non-promotional items provided to health professionals and members of the public and the like; written details of the action taken must be provided 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, 7, 9 or 10 above and indicates that it no longer wishes to accept the jurisdiction of the Authority, the Appeal Board may decide to remove the company from the list of non member companies which have agreed to comply with the Code and advise the Medicines and Healthcare Products Regulatory Agency that responsibility for that company under the Code can no longer be accepted.

The ABPI Board 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 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 ABPI Board. Such a report may be made notwithstanding the fact that the company has provided an undertaking requested by either the Panel or the Appeal Board.

12.2 Where such a report is made to the ABPI Board, the ABPI Board may suspend or expel the company from the ABPI.

In the case of a company not in membership of the ABPI, the ABPI Board may remove the company from the list of non member companies which have agreed to comply with the Code and advise the Medicines and Healthcare Products Regulatory Agency that responsibility for that company under the Code can no longer be accepted.

To assist it in deciding whether to suspend or expel a company or, in the case of a company not in membership of the ABPI, to remove the company from the list of non member companies which have agreed to comply with the Code, the ABPI Board may require an audit of the company's procedures in relation to the Code to be carried out by the Authority.

12.3 If a member of the ABPI Board 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 ABPI Board during its consideration.

The company concerned is advised in advance of the membership of the ABPI Board and asked if it

has any objections to particular members and the grounds for such objections. Any member in respect of whom there are valid objections must withdraw from the ABPI Board during consideration of the report. The President (or Chairman in the absence of the President) determines whether objections are valid.

Members of the ABPI Board must declare any other interest in a report prior to its consideration. Having consulted the company representative(s) (if present), the President (or Chairman in the absence of the President) determines whether it is appropriate for a particular member to remain for the consideration of the report.

12.4 Where a report is made to the ABPI Board 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 ABPI Board 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.

Where expert assistance has been obtained by either the Panel or the 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 sent 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 for information following publication.

13.5 Full case reports in printed form are published each quarter by the Authority.

Copies of the reports are sent to the Medicines and Healthcare Products Regulatory Agency, the Competition and Markets Authority, the Serious Fraud Office, the British Medical Association, the Royal Pharmaceutical Society, 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 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.

The Authority's website also carries interim case reports in respect of cases where publication of the final report is delayed because either the Appeal Board or the ABPI Board has required an audit of the respondent company's procedures in relation to the Code.

Access to the Authority's website is unrestricted.

- 13.7 Following publication of the relevant case reports, the Authority advertises in the medical, pharmaceutical and nursing 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. The companies concerned are required to contribute to the cost of the press advertisements.

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 Authority, as referred to in the above procedures, is 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 Authority, but not thereafter.

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

- 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 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, the charges for audits carried out in accordance with Paragraphs 10.4, 11.3 and 12.2 above and the contributions to the cost of press advertisements referred to in Paragraph 13.7 above are determined by the ABPI Board 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 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 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 ruling 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 will be separately liable to pay any administrative charge which is payable.

- 16.4 Where a company advises the Authority that it may have breached the Code, and it is subsequently ruled in breach, any administrative charge payable will be one half of that which would otherwise have been due.

- 16.5 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.

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

17 Scrutiny

- 17.1 The Authority arranges for the scrutiny of samples of advertisements, detail aids, leavepieces, other promotional items and meetings on a continuing basis in relation to the requirements of the Code.

Members of the Authority must not carry out scrutiny.

To facilitate such scrutiny, the Director may 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.

- 17.2 Where a possible breach of the Code is identified under this procedure by the scrutineer, the company concerned is requested to comment in writing within ten working days of receipt of the notification.
- 17.3 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 will be payable in these circumstances and there will be no case report on the matter in question.
- 17.4 If the company does not accept that there is a breach of the Code and, having considered the company's comments, the scrutineer decides that there is no case to answer under the Code, then the procedure is brought to a close. There will be no case report on the matter in question.
- 17.5 If the company does not accept that there is a breach of the Code but, having considered the company's comments, the scrutineer considers that a case has been established, the matter will be dealt with as a complaint.

18 Provision of Advice and Assistance with Conciliation

- 18.1 The 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 Appeal Board.
- 18.2 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.

19 Amendments to the Code of Practice and Constitution and Procedure

- 19.1 The Code and this Constitution and Procedure may be amended by a simple majority of those present and voting at a General Meeting of the ABPI.

Notwithstanding the above, where a proposal to amend the Code or this Constitution and Procedure arises solely from the ABPI's obligation to comply with any code promulgated by the European Federation of Pharmaceutical Industries and Associations (EFPIA), then the ABPI Board may decide that formal approval at an ABPI General Meeting is not necessary. ABPI member companies must nonetheless be consulted in relation to the proposed texts of the changes.

- 19.2 The views of the Authority and the 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 Competition and Markets Authority, the Serious Fraud Office, the British Medical Association, the Royal Pharmaceutical Society and the Royal College of Nursing must also be invited.

Notwithstanding the above, where the ABPI Board has decided, in accordance with Paragraph 19.1 above, that formal approval of the proposal at an ABPI General Meeting is not necessary, then the bodies referred to above need only be informed of the changes which are to be made.

- 19.3 The Authority and the Appeal Board may, in the light of their experience, make recommendations for amendment of the Code and this Constitution and Procedure.

20 Annual Report

An annual report of the Authority is published each year with the approval of the Appeal Board. This report includes details of the work of the Authority, the 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 or 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.

Some of the changes made in the 2015 Code are mentioned in these guidelines but companies should review the documentation sent out by the PMCPA in relation to the 2015 Code to ensure that they are fully in compliance.

In the 2015 Code, the term 'appropriate administrative staff' has been replaced by 'other relevant decision makers', the latter being defined in Clause 1.5.

It should be noted that Clause 19 and subsequent clauses in the 2014 Code have been renumbered and, in some instances, rearranged, in the 2015 Code.

The guidelines do not cover all aspects of the Code and are thus no substitute for a detailed study of the Code as a whole, including all of the supplementary information.

1) Scope of the Code

It should be borne in mind that the Code covers some matters that are not necessarily related to promotion. Companies should familiarise themselves with the detail of what is covered and ensure that their procedures are such as to ensure compliance at all times. The supplementary information to Clause 1.1 gives guidance in this regard as does Clause 14.3 which details materials to be certified even if they are non-promotional in nature.

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 non-promotional material could be used or made available in such a way that it would be considered promotion and thereby come within the scope of the Code.

2) Co-Promotion

Adequate provision should be made in co-promotion agreements and the like to ensure compliance with the Code. Where companies jointly promote the same product and the promotional material bears both company names, the companies concerned will be held jointly responsible for it under the Code.

As an alternative to each company separately certifying joint materials, a change made in the 2015 Code allows the companies concerned to agree to have only two final signatories to certify on behalf of all of the companies. This must be agreed beforehand and the PMCPA and the MHRA notified in advance as to whom the signatories will be. In the event of a complaint, each company concerned would remain responsible under the Code (supplementary information to Clause 14.1).

3) Breaches of the Code

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

Procedures must be in place to ensure that material found to be in breach of the Code, and any similar material in any format, is quickly and entirely withdrawn from use, not forgetting material stored electronically and/or in the hands of others, such as printers and agencies. It is important for the reputation of the industry that companies comply with undertakings. Inadequate action leading to a breach of undertaking is likely to be in breach of Clause 2.

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

4) Compliance

Companies should bear in mind that promotional material must be up-to-date at the time that it is sent or used or, in the case of a journal advertisement, at the publication date of the journal.

Each company must have a senior employee who is responsible for ensuring that it meets the requirements of the Code (Clause 1.12).

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.

To assist with compliance, companies should have a comprehensive set of standard operating procedures (SOPs) covering all aspects of the Code.

SOPs should set out high standards and relevant staff should be trained and validated on their content.

5) **Price Lists for Unlicensed Medicines**

Price lists relating to unlicensed medicines are allowed provided that they include no product claims and make clear that the products are unlicensed (Clause 1.2 and its supplementary information). Such price lists can be sent to health professionals and other relevant decision makers at reasonable intervals or in response to enquiries. They must not be used proactively in a manner which could be seen to be promoting unlicensed medicines, such as by displaying them on exhibition stands.

6) **Advance Notification of New Products and Product Changes**

In the 2015 Code, the requirements have been amended to make it clearer that advance notification applies to products or changes which may significantly affect expenditure, which could be significant additional cost or significant savings.

The 2015 Code states that wherever possible information should be provided for inclusion in national horizon scanning databases (supplementary information to Clause 3.1).

7) **Prescribing Information**

In certain circumstances Clause 4 of the 2015 Code allows elements of the prescribing information to be provided by way of a copy of the summary of product characteristics.

New supplementary information to Clause 4.4 in the 2015 Code covers the use of links to prescribing information. Digital material should provide a link to prescribing information on another website only where the material is expected to be viewed online, such as advertisements in electronic journals.

8) **Abbreviated Advertisements**

Abbreviated advertisements (Clause 5) must refer to a website where further information about the product can be found. This further information can consist of the prescribing information, as set out in Clauses 4.2 and 4.3, or the summary of product characteristics. Clause 5.4 sets out the information which must be given.

9) **Extremes of Format**

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

All informational or educational materials must be inexpensive, directly relevant to the practice of medicine or pharmacy and directly beneficial to the care of patients.

10) **Clinical Trials**

Companies must disclose details of clinical trials (Clause 13.1). The supplementary information to

Clause 13.1 details how this should be done. Companies must include, on the homepage of their website, information as to where details of their clinical trials can be found.

11) **Non-Interventional Studies of Marketed Medicines**

A non-interventional study of a marketed medicine is a study where the medicine is prescribed in the usual manner in accordance with the terms of its marketing authorization (Clause 13.2). The assignment of the patient to a particular therapeutic strategy is not decided by a study protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures are applied to the patients and epidemiological methods are used for the analysis of collected data.

A company involved in non-interventional studies must have a scientific service to deal with their approval and supervision as required by Clause 25.2.

Companies must publish the summary details and results of non-interventional studies of marketed medicines completed on or after 1 May 2011 (Clause 13.3). This applies to studies with which a UK company has had any involvement. The 2008 Code encouraged companies to publish this information and this still applies to studies completed prior to 1 May 2011.

Clause 13.4, which sets out the criteria with which non-interventional studies must comply, applies to studies completed on or after 1 July 2008, though companies are encouraged to comply in relation to studies completed prior to that date.

12) **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
- the names of signatories are notified in advance to the Advertising Standards Unit, Vigilance and Risk Management of Medicines 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); much more frequent recertification may be needed for some products and companies should ensure that the status of material continuing in use is kept under review
- paper or electronic copies of 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.

In the 2015 Code, the supplementary information to Clause 14.1 sets out a procedure to cover the situation where material certified in an electronic form is subsequently printed. Any one of the company's signatories can check and sign the item in its final printed form. There would thus be two certificates and both must be preserved.

13) Certification of Representatives' Briefing and Training Materials

The certification requirements of Clause 14 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.

14) Certification of Items to be Passed on to Patients

Items which are provided to health professionals for them to pass on to patients must be certified (Clauses 14.3 and 18.2). Such items must be part of a formal patient support programme, the details of which must be appropriately documented and certified in advance.

15) Certification of Other Material

Clause 14.3 lists other material which needs to be certified and companies should familiarise themselves with what is covered. Additionally, Clause 14.2 requires the certification of all meetings which involve travel outside the UK. This does not apply if the company's only involvement is to support a speaker to present at the meeting. The Code now allows only very limited provision to health professionals of promotional aids for them to keep and these must be certified (supplementary information to Clause 18.3 and Clause 14.1).

16) 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.

17) Representatives' Training

Procedures must ensure that:

- representatives are aware that they must maintain a high standard of ethical conduct and comply with all relevant requirements of the Code (Clause 15.2)
- 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 Clause 16.3 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 Clause 16.3 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. It is recommended that each representative is given their own copy of the Code. 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 adverse reactions (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 medicines 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.

18) Training

It should be ensured that all relevant personnel, including representatives, members of staff and others retained by way of contract, 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 other relevant decision makers 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 it is recommended that key personnel attend one of the seminars organised by the Prescription Medicines Code of Practice Authority.

All personnel (and others retained by way of contract) must be fully conversant with pharmacovigilance requirements relevant to their work and this must be 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, are circulated to relevant personnel.

Companies should consider making knowledge of, and compliance with, their obligations in relation to both the Code and pharmacovigilance requirements part of the annual appraisal process for relevant employees.

Clause 16.3 sets out the requirements relating to the need for representatives to pass an appropriate examination. Examination status is enquired into when a complaint is received about a representative. Companies should have appropriate procedures in place to ensure that representatives enter for the examination on the earliest practicable date.

Representatives must take the examination in their first year of such employment and must pass it within two years of starting such employment.

A significant change made in the 2014 Code was that the examinations would in due course have to be accredited to at least Level 3 by an external awarding body recognised by Ofqual. The ABPI is now offering accredited examinations and will cease to offer its unaccredited examinations at the end of 2015. Examinations may also be offered by providers other than the ABPI (Clause 16.3).

Representatives commencing such employment on or after 1 October 2014 must take an accredited examination. It is recommended that representatives commencing such employment on or after 1 January 2014 but on or before 30 September 2014 also take an accredited examination. There is more detail in the supplementary information to Clause 16.3.

19) Provision of Medicines and Samples

Companies should ensure that their procedures are such as to ensure compliance with Clause 17. They should be clear as to the distinctions between samples, identification samples, titration packs and free goods etc which are described in the supplementary information to Clause 17.

Electronic signatures are acceptable in relation to requests for samples.

Not more than four samples of a particular medicine may be provided to an individual health professional during the course of a year (Clause 17.2).

Samples of a medicine can be provided to a health professional for only two years after that health professional first requests samples of it. There is a special provision for the sampling of new medicines which are extensions of existing medicines (Clause 17.2).

Medicines covered by Clause 17.6 cannot be provided as samples at all.

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 (Clause 17.2).

Samples must not be given for the sole purpose of treating patients (Clause 17.12).

Starter packs are not permitted (supplementary information to Clause 17). Starter packs were 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.

20) Items for Patients and Promotional Aids

The traditional forms of promotional aid, such as coffee mugs, stationery and calendars, cannot be given to health professionals and nor can items for use in a clinic or treatment room, such as surgical gloves, tongue depressors, tissues and the like (supplementary information to Clause 18.1). Toys and puzzles for children to play with cannot be provided either.

Items intended to be passed on to patients can be provided to health professionals if these are part of a patient support programme, the details of which have been appropriately documented and certified in advance (Clause 18.2). They must cost no more than £6, excluding VAT, and the perceived value to the health professional and the patient must be similar. They must directly benefit patient care. Such items can be provided to health professionals by representatives during the course of a promotional call but they must not be given out from exhibition stands.

In limited circumstances, patient support items can be provided to health professionals when they are not to be passed to patients for them to keep (supplementary information to Clause 18.2). This is where their purpose is to allow patients to gain experience in using their medicines whilst under the supervision of a health professional. Examples are inhalation devices devoid of active ingredients and devices to assist patients to learn how to self-inject.

The only items that can be provided to health professionals for them to keep are notebooks, pens and pencils for use at *bona fide* meetings and conferences etc. No individual should receive more than one notebook and one pen or pencil. The total cost of such items provided to an individual must not exceed £6, excluding VAT, and the perceived value to the recipient must be similar. They must not bear the name of a medicine or any information about medicines but may bear the name of the company providing them (Clause 18.3). They must not be provided by representatives when calling upon health professionals. They must not be given out from exhibition stands. They can be included in conference bags at third party meetings but cannot then bear the name of the company providing them.

Memory sticks and DVDs provided in accordance with the supplementary information to Clause 18.1 must be inexpensive.

There is much detail in the supplementary information to Clauses 18.1, 18.2 and 18.3 and it is essential that companies familiarise themselves with it.

21) Medical and Educational Goods and Services

The provision of medical and education goods and services must be carried out in compliance with Clause 19 and must be certified in accordance with Clause 14.3.

There is much detail in the supplementary information to Clause 19.1.

22) Joint Working, Outcome Agreements, Patient Access Schemes and Package Deals

Joint working between the NHS and the pharmaceutical industry is dealt with in the Code in some detail (Clause 20). An executive summary of a joint working agreement must be made public in relation to joint working projects starting on or after 1 May 2011 or on-going on that date. Material relating to joint working must be certified (Clause 14.3).

The Code requires public disclosure of transfers of value in connection with joint working. This applies to transfers of value made in 2015 and each calendar year thereafter (Clause 20). Disclosure of 2015 data will be required in 2016. Clause 24 sets out the requirements in relation to transfers of value.

The supplementary information to Clause 18.1 deals with outcome or risk sharing agreements, patient access schemes and package deals.

23) Donations and Grants to Institutions, Organisations and Associations

Clause 18.6 of the 2011 Code required pharmaceutical companies to make publicly available details of grants and donations made to institutions, organisations and associations. This applied to donations and grants made in 2012 and each calendar year thereafter.

The 2014 Code introduced requirements for public disclosure which differed from those in the Second 2012 Code. The new requirements apply to transfers of value made in 2015 and each calendar year thereafter. Disclosure of 2015 data will be required in 2016. Clause 24 sets out the requirements in relation to transfers of value.

For disclosures in relation to calendar years 2013 and 2014, the requirements and procedures in Clause 18.6 and its supplementary information in the Second 2012 Edition of the Code continue to apply.

The Code now requires public disclosure of transfers of value in relation to contracts under which institutions etc provide services to pharmaceutical companies (Clause 21 and its supplementary information). This will apply to data for 2015 and each calendar year thereafter. Disclosure must be carried out in accordance with Clause 24.

24) 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 22.

Clause 22.2 stipulates that the cost of a meal (including drinks) provided by way of subsistence must not exceed £75 per person excluding VAT and gratuities. The supplementary information to Clause 22.2 sets out further details. The maximum of £75 plus VAT and gratuities does not apply to meetings held in European countries where the national association is a member of EFPIA. The local limit would apply instead. Information is available at EFPIA.eu.

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 22.1).

Meetings which involve travel outside the UK must be formally certified as set out in Clause 14.2. This does not apply if the company's only involvement is to support a speaker to present at the meeting.

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

Companies should remind their affiliates that the ABPI Code of Practice must be complied with if UK health professionals attend meetings which they organise regardless of whether such meetings occur in the UK or abroad.

25) Sponsorship to Attend Meetings

The 2011 Code required financial details of sponsorship of UK health professionals and appropriate administrative staff to attend meetings organised by third parties to be made publicly available.

The information had to be made publicly available in respect of sponsorship to attend meetings in 2012 and each calendar year thereafter.

The 2014 Code introduced different requirements which applied to both meetings organised by third parties and those organised by pharmaceutical companies. The previous requirements in the Second 2012 Code applied only to meetings organised by third parties.

Disclosure will be of attendance at meetings in 2015 and each calendar year thereafter. Disclosure of 2015 data will be required in 2016 (Clause 22.5 and its supplementary information). Disclosure must be carried out in accordance with Clause 24.

For disclosure in relation to calendar years 2013 and 2014 the requirements and procedures in Clause 19.4 and its supplementary information in the Second 2012 Edition of the Code still apply.

26) The Use of Consultants

Health professionals and other relevant decision makers may be used as consultants and advisors for services such as speaking at and chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or travel. The arrangements which cover these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil the criteria set out in Clause 23 and procedures should ensure that the requirements of that clause are complied with.

Changes were made in relation to the use of consultants in the 2011 Code. In particular, public disclosure of fees paid to consultants in the UK for certain services would be required for payments made in 2012 and each calendar year thereafter (Clause 20.2). No disclosure was required in relation to payments for research and development work, including the conduct of clinical trials. Additional information would have to be disclosed in relation to certain payments made in 2013 and each calendar year thereafter (Clause 20.3).

The 2014 Code made significant changes in relation to transfers of value to consultants. Transfers of value in relation to research and development work (including the conduct of clinical trials) were now included but were to be disclosed on an aggregate basis.

The new requirements apply to data for 2015 and each calendar year thereafter. The data for 2015 will be disclosed in 2016. Disclosure must be carried out in accordance with Clause 24. There is much detail in the supplementary information to Clauses 23.2 and 23.3.

For disclosures in relation to calendar years 2013 and 2014, the requirements and procedures in Clauses 20.2 and 20.3 and their supplementary information in the Second 2012 Edition of the Code still apply.

Contracts or agreements with consultants entered into or renewed on and after 1 May 2011 must include provisions regarding their obligation to declare the arrangement whenever they write or speak in public about the subject of the agreement or any issue relating to the company (Clause 23.1). Companies are encouraged to renegotiate existing contracts to include such provisions at their earliest convenience.

27) Transfers of value

Transfers of value to health professionals and healthcare organisations must be disclosed (Clause 24). The term 'transfer of value' is defined in Clause 1.10 and the supplementary information to Clause 1.10 lists a number of matters which are not transfers of value for the purposes of the Code. Clause 24.2 lists transfers of value covered by Clause 24.1. Transfers of value to patient organisations are not covered by Clause 24. These transfers of value continue to be covered by Clauses 27.7 and 27.8.

The matter is complicated as far as the Code is concerned by the fact that it already had disclosure requirements, some of which will be superseded in due course by the new requirements which are derived from the new EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations.

The new requirements involve the disclosure of 2015 data in 2016. The existing requirements relate to the disclosure of 2012 and 2013 data onwards and these requirements will continue to apply until the new requirements supersede them.

References to the new requirements are made at relevant places in these Guidelines. Disclosures must be made in accordance with Clause 24.

Companies must disclose using the central UK platform and a standard template (supplementary information to Clause 24.1).

Companies should take steps to ensure that they will be able to readily source the information to be publicly disclosed.

28) Scientific Services

Companies must ensure that they have an identifiable scientific service to compile and collate all information, from medical representatives or any other source, about the medicines which they market (Clause 25.1). Where relevant, they must also have a scientific service to deal with the approval and supervision of non-interventional studies (Clause 25.2). There can be one scientific service in charge of both responsibilities or separate services with clearly delineated duties.

29) 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 26.

Any material which relates to a medicine and which is intended for patients taking that medicine must include a statement relating to the reporting of side effects. If the medicine is one which is subject to additional monitoring, then the material must include an inverted black equilateral triangle and an additional statement (Clause 26.3).

30) 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 (Clause 27).

When working with patient organisations, companies must ensure that all of the arrangements comply with the Code. This includes the prohibition on advertising prescription only medicines to the public (Clause 26.1). The requirements of Clause 22, which covers meetings for health professionals and other relevant decision makers, also apply to pharmaceutical companies supporting patient organisation meetings.

Companies must ensure that the requirements of Clause 27 are complied with when working with patient organisations. In particular, written agreements must be in place in respect of every significant activity or ongoing relationship (Clause 27.3) and there has to be public disclosure of financial support or indirect/non financial support. The published information must include the monetary value of financial support and of invoiced costs (Clause 27.7). For significant non-financial support that cannot be assigned a meaningful monetary value, the published information must describe clearly the non-monetary value that the organisation receives.

Companies must ensure that their support is clearly acknowledged from the outset. The wording of a declaration of sponsorship must accurately reflect the nature of a company's involvement.

Contracts under which patient organisations provide consultancy or other services to companies are subject to the Code and Clause 27.8 specifies the criteria which contracts for such services must meet, to the extent relevant to the particular arrangement.

A list of patient organisations that have been engaged to provide significant contracted services must be published and updated at least once a year.

Companies should ensure that such contracts comply with the criteria in Clause 27.8.

Hospitality can be provided in certain circumstances to patient carers (supplementary information to Clause 27.2).

31) The Internet

Companies should ensure that all relevant requirements of the Code, including Clause 28, are complied with in relation to promotional material for prescription only medicines which is provided on the Internet and directed to a UK audience.

If access to such material is not limited to health professionals and other relevant decision makers, 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 clearly separated and the intended audiences identified.

Material intended for the public which is provided on the Internet must comply with Clause 28.2.

LEGISLATION, OTHER CODES *and* GUIDELINES

LEGISLATION

The Human Medicines Regulations 2012
2012 No. 1916

The Human Medicines
(Amendment) (No.2) Regulations
2014 No. 1878

The Consumer Protection from Unfair Trading
Regulations 2008
2008 No. 1277

Directive 2001/83/EC on the Community Code relating
to medicinal products for human use, as amended by
Directive 2004/27/EC

Bribery Act 2010

OTHER CODES

International

IFPMA Code of Practice (International Federation of
Pharmaceutical Manufacturers and Associations)

EFPIA Code on the Promotion of Prescription-Only
Medicines to, and Interactions with, Healthcare
Professionals

EFPIA Code of Practice on Relationships between the
Pharmaceutical Industry and Patient Organisations

EFPIA Code on Disclosure of Transfers of Value from
Pharmaceutical Companies to Healthcare Professionals
and Healthcare Organisations

(European Federation of Pharmaceutical Industries and
Associations – EFPIA)

WHO Ethical Criteria for Medicinal Drug Promotion,
Geneva 1988 (World Health Organisation)

IPCAA Healthcare Congress Guidelines (International
Pharmaceutical Congress Advisory Association)

United Kingdom

The UK Code of Non-broadcast Advertising, Sales
Promotion and Direct Marketing (Committee of
Advertising Practice/ Advertising Standards Authority)

Codes of Practice for Advertising Over-the-Counter
Medicines – the PAGB Consumer Code and the PAGB
Professional Code (Proprietary Association of Great
Britain – PAGB)

BMA ‘Medical ethics today’ (British Medical
Association)

General Medical Council ‘Good Medical Practice’

General Pharmaceutical Council ‘Standards of conduct,
ethics and performance’

Nursing & Midwifery Council ‘Standards of conduct,
performance and ethics for nurses and midwives’

Department of Health ‘Commercial sponsorship –
Ethical standards for the NHS’

Department of Health ‘Standards of Business Conduct
for NHS Staff’

GUIDELINES

Advertising and Promotion of Medicines in the UK
(2014) – The Blue Guide (Medicines and Healthcare
Products Regulatory Agency). It includes Disease
Awareness Campaigns Guidelines and Medicines –
Guidance for the pharmaceutical industry

Best practice guidance on joint working between the
NHS and the pharmaceutical industry and other
relevant commercial organisations (Department of
Health)

Moving beyond sponsorship: interactive toolkit for
joint working between the NHS and the pharmaceutical
industry (Department of Health/ ABPI)

ABPI Guidance notes on joint working between
pharmaceutical companies and the NHS and others for
the benefit of patients

Joint Position on the Disclosure of Clinical Trial
Information via Clinical Trial Registries and Databases
2009 (<http://clinicaltrials.ifpma.org>)

Joint Position on the Publication of Clinical Trial Results
in the Scientific Literature 2010
(<http://clinicaltrials.ifpma.org>)

Guidelines on Standards in Medical Information
(Pharmaceutical Information & Pharmacovigilance
Association)

The Legal & Ethical Guidelines for Healthcare Market
Research (British Healthcare Business Intelligence
Association/ ABPI)

PMCPA GUIDANCE NOTES

Guidance about Certification (including certification of
multi company projects)

Guidance about Clause 3

Guidance about Digital Communications

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