AGREED AMENDMENTS
TO THE 2015
ABPI CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY

Some of the changes relate to the move from aggregated disclosure to individual disclosure and the implementation of the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (EFPIA Disclosure Code). Other changes reflect the outcome of the ABPI Board review of the Code (2015), views of the ABPI Board of Management, the change to the accredited ABPI examination as well as the usual tidying up.

All agreed proposals are included in this document. The proposals were agreed at ABPI meetings on 11 November and 1 December 2015.

CLAUSE 1 – Scope of the Code and Definition of Certain Terms

Clause 1.1 Supplementary Information – Joint Working

Current text

'*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.'

Amendment

Second and third paragraphs deleted and the first paragraph amended to include the reference in the fourth paragraph to Clause 20 and its supplementary information.

To read:

'*Joint working with the NHS and others is permitted if carried out in a manner compatible with the Code. The Department of Health definition of joint working and other information including the conduct of joint working is covered in Clause 20 and its supplementary information.*'

* * * * *

Clause 1.10

Current text

‘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.’

Amendment

Amended to link disclosure to when the company knows or can identify the recipient rather than when the recipient can identify the company.

To read:

‘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 on behalf of a company for the benefit of a recipient or through an intermediate and where the company knows or can identify the recipient that will benefit from the transfer of value.’

* * * * *

CLAUSE 4 – Prescribing Information and Other Obligatory Information

Clause 4.2

Current text

‘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 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.'

Amendment

New supplementary information to Clause 4.2 added to explain the use of the summary of product characteristics as a means of providing information required in Clause 4.2 i – viii.

To read:

'*Clause 4.2 Use of the summary of product characteristics.*

The Code defines prescribing information to consist of three parts, the legal classification, the cost and other elements (listed as i-viii) in Clause 4.2. In certain situations elements i-viii can be provided by the summary of product characteristics. However, in some circumstances, elements i-viii will have to be provided either as described in Clause 4.2 or by reproducing the summary of product characteristics. Where there are issues of space on printed material, for example a journal advertisement, then elements i-viii will probably have to be provided as a summary. Where there is no issue of space – perhaps a detail aid, elements i-viii could be provided by reproducing the summary of product characteristics. With an electronic advertisement elements i-viii could be provided by a link to the summary of product characteristics (Clause 4.4 and its supplementary information). It would not be acceptable to provide a website address for the summary of product characteristics on a printed journal advertisement as a means of meeting the requirements to provide elements i-viii.'

* * * * *

Clause 4.8

Current text

'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.'

Amendment

Deleted.

* * * * *

CLAUSE 11 – Distribution of Material

Clause 11.1 Supplementary Information – Distribution of Promotional Material

Current text

'*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.'*

Amendment

The reference to 'Promotional' in the heading and the first reference to 'promotional' have been deleted.

To read:

'Clause 11.1 Supplementary Information – Distribution of Material

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 14 – Certification

Clause 14.1

Current text

'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.'

Amendment

Changed from two persons for certification to one person who must be either a registered medical practitioner or a pharmacist registered in the UK. In addition the signatory must not be responsible for developing or drawing up the material.

To read:

'Promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by one person on behalf of the company in the manner provided for by this clause. This person 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 person certifying on behalf of the company must not be the person responsible for developing or drawing up the material.

* * * * *

Clause 14.1 Supplementary Information – Joint Ventures and Co-Promotion

Current text (extract)

'*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.*'

Amendment

'Two final signatories' and 'signatories' replaced with 'one final signatory' and 'signatory'.

To read:

'*Under co-promotion arrangements or other arrangements where companies work together, such as joint working projects, the companies concerned can agree to have only one final signatory 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 signatory 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

Current text

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.

Amendment

The requirements for certification of certain meetings held outside the UK which involve UK delegates amended.

To require examination by the UK company rather than certification of meeting arrangements in certain circumstances including when the UK company has involvement but does not fund delegates or speakers.

To read:

'14.2 All meetings involving travel outside the UK where a UK company funds UK delegates must be certified in advance in a manner similar to that provided for by Clause 14.1.

In addition, all meetings involving travel outside the UK that are wholly or mainly for UK delegates must also be certified in advance in a manner similar to that provided for by Clause 14.1.

Clause 14.2 Supplementary Information – Meetings Involving Travel Outside the UK

Amendment

The current supplementary information (2015 Code) and the changes agreed in November 2015 replaced.

To read:

'UK Companies have responsibilities under the Code for meetings which they organise and when UK delegates and/or UK speakers are invited or supported to go to meetings outside the UK. Clauses 23 and 24 in relation to disclosure of transfers of value will also need to be followed.

When certifying arrangements for meetings which involve travel outside the UK all the relevant documents and arrangements must be considered 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.

If the company's only involvement is to support a speaker to present at the meeting and there is no pharmaceutical company involvement with the meeting at all, for example a learned society meeting, then neither certification nor examination is required.

If a UK company's only role for meetings which are not wholly or mainly for UK delegates is to select or invite but not fund UK speakers and/or delegates, then the arrangements for such meetings should be examined by the UK company to ensure they do not contravene the Code or relevant statutory requirements.

There is no requirement to certify arrangements for meetings held outside the UK that are wholly organised and/or funded by any overseas legal entity of a pharmaceutical company even if UK delegates are selected and invited by the overseas company unless such meetings are wholly or mainly for UK delegates. The UK company must be informed and the arrangements for meetings which involve UK delegates travelling outside the UK where the UK company has not funded the delegates should be examined by the UK company to ensure they do not contravene the Code or the relevant statutory requirements.'

Clause 14.2 Supplementary Information – Presentations by UK speakers at Meetings Held Outside the UK

Amendment

The current Clause 14.2 (2015 Code) and supplementary information agreed in November 2015 replaced.

To read:

'When a pharmaceutical company based outside the UK arranges via a UK company for a UK speaker to present at a meeting to be held outside the UK then that speaker's presentation materials do not need to be certified or examined by the UK provided there are no UK delegates and the UK company has no role whatsoever in relation to the meeting or the presentation. In such circumstances the meeting arrangements, in as much as they apply to the UK speaker, will not have to be certified or examined.'

* * * * *

Clause 14.4

Current text

'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.'

Amendment

The first part of the clause amended to refer to signatories as set out in Clause 14.1

To read:

'The names of those nominated as signatories as set out in Clause 14.1, 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.'

* * * * *

Clause 14.5

Current text

‘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.’

Amendment

Paragraphs 1, 2 and 4 changed from signatories to signatory.

To read:

‘The certificate for promotional material must certify that the signatory has examined the final form of the material to ensure that in his/her 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 certificate for material covered by Clause 14.3 above must certify that the signatory has looked at the final form of the material to ensure that in his/her 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 signatory has examined all the proposed arrangements for the meeting and that in his/her belief the arrangements are in accordance with the relevant regulations relating to advertising and the Code.’

* * * * *

CLAUSE 15 – Representatives

Clause 15.3 Supplementary Information – Health Professionals’ Codes of Conduct

Current text

'*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".'

Amendment

Shortened.

To read:

'*The General Medical Council, the General Pharmaceutical Council and the Code of the Nursing & Midwifery Council, set out requirements for doctors, pharmacists, pharmacy technicians, nurses and midwives. Further details are given in the supplementary information to Clauses 18.1 and 22.*'

* * * * *

CLAUSE 16 – Training

Clause 16.3 Supplementary Information – Introduction of Accredited Examinations

Current text (extract)

'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.'

Amendment

Amended to reflect the withdrawal of the unaccredited examination.

To read:

'*Representatives commencing such employment on or after 1 October 2014 must take an accredited examination. It was recommended that representatives commencing such employment between 1 January 2014 and 30 September 2014 also took an accredited examination.*

The unaccredited examination ceased on 31 December 2015 and therefore a candidate who has passed part of an unaccredited ABPI examination but did not complete it by 31 December 2015 will have to 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.'

* * * * *

CLAUSE 17 – Provision of Medicines and Samples

Clauses 17.7 and 17.8

Current text

'**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.

Amendment

Clauses deleted and text moved to a new second paragraph in the existing supplementary information to Clause 17.9 Control and Accountability.

To read:

'*Samples distributed by representatives must be handed direct to the health professionals requesting them or persons authorized to receive them on their behalf. The provision of medicines and samples in hospitals must comply with individual hospital requirements.*'

* * * * *

CLAUSE 18 – Prohibition on Inducements etc

Clause 18 Supplementary Information – Promotional Aids

Current text (extract)

'*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.'

Amendment

First sentence deleted.

To read:

'*Advertisements for prescription medicines must not appear on any items, such as diaries and desk pads, which pharmaceutical companies could not themselves give.*'

* * * * *

CLAUSE 19 – Medical and Educational Goods and Services

Clause 19 Supplementary Information – Disclosure for Calendar Years 2013 and 2014

Current text

'*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.*'

Amendment

Deleted.

* * * * *

Clause 19.1 Supplementary Information – Medical and Educational Goods and Services

Current text (extract)

'*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.*'

Amendment

Amended to delete 'by the Code of Practice signatories within companies to ensure that the requirements of the Code are met' as the cross reference to Clause 14.3 covered the point.

To read:

'*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 as required by Clause 14.3.*'

* * * * *

CLAUSE 20 – Joint Working

Clause 20 Supplementary Information – Joint Working

Current text (extract)

'*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.*'

Amendment

Amended so that the joint working agreement does not have to be certified.

To read:

'*Attention is drawn to the certification requirements set out in Clause 14.3 which apply to material relating to joint working including the project initiation documentation and the executive summary of the joint working agreement. Only the final documents etc for any joint working project need to 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. The joint working agreement does not need to be certified.*'

* * * * *

CLAUSE 22 – Meetings, Hospitality and Sponsorship

Clause 22 Supplementary Information – Disclosure for Calendar Years 2013 and 2014

Current text

'***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.'

Amendment

Deleted.

* * * * *

CLAUSE 23 – The Use of Consultants

Clause 23 Supplementary Information – The Use of Consultants

Current text (extract)

'*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.'

Amendment

The references to renegotiating existing contracts and limited market research have been deleted.

To read:

'*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 a renewed on or after 1 May 2011.'*

* * * * *

Clause 23 Supplementary Information – Disclosure for Calendar Years 2013 and 2014

Current text

'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.'

Amendment

Deleted.

* * * * *

CLAUSE 24 – Transfers of Value to Health Professionals and Healthcare Organisations

Clause 24.1 Supplementary Information – Date of Implementation

Current text (extract)

'*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 of 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.*'

Amendment

Deleted.

* * * * *

Clause 24.9 Supplementary Information – Aggregate disclosure

Amendment

Supplementary information added in relation to an approach to the situation when one health professional gives consent to disclose some but not all transfers of value from a company.

To read:

'24.9 Disclosure of Transfers of Value to Individuals

If an individual health professional or other relevant decision maker receives a number of transfers of value from a company and decides not to agree to disclosure of one or more of those transfers of value, then that company can disclose all of that individual's transfers of value in its aggregate amount.'

* * * * *

CLAUSE 26 – Relations with the Public and the Media

Clause 26.5

Current text

'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.'

Amendment

Deleted.

* * * * *

CLAUSE 27 – Relationships with Patient Organisations

Clause 27.3 Supplementary Information – Written Agreements

Current text

'*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.'

Amendment

Amended to make it clear that written agreements need to be certified.

To read:

'*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.*

The written agreement must be certified as set out in Clause 14.3.'

* * * * *

Clause 27.8

Current text

'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.

Patients 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 patients 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 patients 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.'

Amendment

New supplementary information added to make it clear that when patients organisations are contracted to provide services to companies these contracts do not have to be certified.

To read:

'***Clause 27.8 Supplementary Information – Consultancy Services Provided by Patient Organisations***

When companies engage patient organisations to provide services under Clause 27.8 the contracts for those services do not need to be certified.'

* * * * *

GENERAL

The names of organisations, titles of publications and similar factual matters in the Code of Practice booklet updated.

* * * * *

Transition Arrangement

A statement at the beginning of the Code of Practice booklet to read:

'This edition of the Code of Practice comes into operation on 1 January 2016. During the period 1 January 2016 to 30 April 2016, 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.'

* * * * *

2 December 2015