

AMENDMENTS
TO THE
CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY
2006 EDITION

CLAUSE 1

Supplementary information to Clause 1.1 – Scope of the Code

Amendment

Additional supplementary information is added:

‘Market extension and joint working

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.

Joint working with health authorities and trusts and the like is permitted if carried out in a manner compatible with the Code. Joint working may occur through interaction with those responsible for delivering and administering healthcare.

The Department of Health (DH) 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 pharmaceutical industry* has been launched by the DH and the ABPI.’

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Supplementary information to Clause 1.1 - Scope of the Code

Current text

The current text states, *inter alia*:

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

Amendment

Changed to:

‘Some of the requirements of the Code are not necessarily related to promotion. Examples include declarations of sponsorship in Clause 9.10, non-interventional studies in Clause 13

[new], certain aspects of the provision of medicines and samples in Clause 17, donations, grants and fees for services in Clauses 18.5 [new] and 18.6 [new], the use of consultants in Clause 20 [new], the provision of information to the public in Clause 22 [formerly Clause 20] and relations with patient organisations in Clause 23 [new].

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Supplementary information to Clause 1.1 - Journals with an international distribution

Current text

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

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

It should be noted that the Medicines and Healthcare products Regulatory Agency's guidance 'Advertising and Promotion of Medicines in the UK', The Blue Guide, differs from the above by stating 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 Pharmaceutical Marketing Practices should be borne in mind.'

Amendment

An additional paragraph is added:

'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.'

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Supplementary information to Clause 1.1 Advertising to the public and advertising over-the-counter medicines to health professionals and the retail trade

Current text

'The promotion of medicines to the public for self medication is covered by the Code of Standards of Advertising Practice for Over-the-Counter Medicines of the Proprietary Association

of Great Britain (PAGB). The PAGB also has a Code of Practice for Advertising Over-the-Counter Medicines to Health Professionals and the Retail Trade.'

Amendment

Changed to:

'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 objective of the advertising is to impact sales and/or recommendations to the public.'

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Supplementary information to Clause 1.7 – Applicability of Codes

Amendment

Add a further paragraph:

'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 3**Supplementary information to Clause 3 - Promotion at international meetings*****Current text***

'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 authorised 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 [*inter alia*]:

- the meeting must be a truly international meeting of high scientific standing with a significant proportion of attendees from outside the UK'

Amendment

This condition is changed to:

- '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'

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Supplementary information to Clause 3 – Promotion at international meetings***Current text***

- 'promotional material for a medicine or indication that does not have a UK marketing authorization must be clearly and prominently labelled to that effect'

Amendment

This condition is changed to:

- 'promotional material, other than promotional aids, for a medicine ...'

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Supplementary information to Clause 3 – Promotion at international meetings***Current text***

- 'the name must be given of at least one major industrialised country (such as EU member states, EFTA countries, Australia, Canada, Israel, New Zealand, South Africa and the United States of America) in which the medicine or indication is authorized and it must be stated that registration conditions differ from country to country'

Amendment

This condition is changed to:

- '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'

CLAUSE 4**Supplementary information to Clause 4.1 – Electronic journals*****Current text***

The current text states, *inter alia*:

'If the product is one that is required to show an inverted black triangle on its promotional material then the black triangle symbol should also appear adjacent to the product name. That is not, however, a requirement of the Code (see supplementary information to Clause 4.3).'

Amendment

Changed to:

'If the product is one that is required to show an inverted black triangle on its promotional material then the black triangle symbol must also appear adjacent to the product name (see [new] Clause 4.11). The size must be such that it is easily readable.'

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Supplementary information to Clause 4.3 – Black triangle symbol***Current text***

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

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

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

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

Amendment

The first paragraph is deleted from the supplementary information.

A new clause is added – to be Clause 4.11:

'When required by the licensing authority, all promotional material, other than promotional aids, must show an inverted black triangle to denote that special reporting is required in relation to adverse reactions.'

The second and third paragraphs of the current supplementary information become supplementary information to new Clause 4.11.

A similar amendment is made in relation to abbreviated advertisements in Clause 5 with some re-ordering of that clause.

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Clause 4.10 – Adverse event reporting

Current text

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

The supplementary information to Clause 4.10 states:

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

Amendment

Clause 4.10 is changed to:

‘All promotional material, other than promotional aids, must include the prominent statement “Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to [relevant pharmaceutical company].”’

The supplementary information to Clause 4.10 is changed to:

‘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.’

The obligatory text set out in Clause 4.10 should be used as soon as possible. It must be used on new materials issued on or after 1 November 2008. Materials that currently comply with the 2006 Code in this regard may continue in use until 1 July 2009.’

A similar amendment is made in relation to abbreviated advertisements in Clause 5.

CLAUSE 6**Supplementary information to Clause 6.3 - Journal advertising*****Current text***

The current text states, *inter alia*:

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

Amendment

'A loose' in the second sentence is deleted and replaced with 'An'.

CLAUSE 9

Supplementary information to Clause 9.10 – Declaration of sponsorship

Current text

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

Amendment

A further paragraph is added:

'The declaration must accurately reflect the nature of the company's involvement.'

CLAUSE 10 [becomes Clause 12]

Clause 10.2 - Disguised promotion [now Clause 12.2]

Current text

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

Amendment

Changed to:

'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.'

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Note

Clause 11 becomes Clause 10.

CLAUSE 12 [becomes Clause 11]

Supplementary information to Clause 12.2 [becomes Clause 11.2] - Frequency of mailings

Current text

The final sentence states:

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

Amendment

'... as can mailings about price changes which contain no product claims' is added to that sentence.

A new paragraph is added:

'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 13 [becomes Clause 21]**Clause 13 - Scientific service responsible for information [now Clause 21]*****Current text***

'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.'

Amendment

Title changed to 'Scientific services'.

Existing Clause 13 becomes Clause 13.1 [now Clause 21.1].

A further paragraph is added to become Clause 13.2 [now Clause 21.2]:

'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, where appropriate, a pharmacist, 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.'

Supplementary information is added to Clauses 13.1 and 13.2 [now Clauses 21.1 and 21.2]:

'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.'

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New Clause 21.3***Amendment***

A new clause is added:

'Clause 21.3

Companies must disclose details of clinical trials.'

Supplementary information is added to the new Clause 21.3:

'Clause 21.3 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 patients enrolment) and completed trials for medicines licensed for use in at least one country. Further information can be found in the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases 2005 (<http://clinicaltrials.ifpma.org>).

Details about clinical trials must be limited to factual and non-promotional information. Such information must not constitute promotion to health professionals, appropriate administrative staff or the public.'

CLAUSE 14

Supplementary information to Clause 14.1 – Certification

Current text

The current text states, *inter alia*:

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

Amendment

The final sentence is changed to:

'Paper or electronic copies of certificates and the final form of material etc ...'

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Supplementary information to Clause 14.3 - Certification

Amendment

Supplementary information to Clause 14.3 is added as a new paragraph:

'The examination of non-interventional studies is dealt with in Clause 21.2 [new] and is not covered by Clause 14.'

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Clause 14.6 Certification

Current text

Clause 14.6 states, *inter alia*,:

'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.'

Amendment

A further paragraph is added:

'Certificates relating to educational material for the public or patients and non-promotional material for patients or health professionals relating to the provision of medical and educational goods and services 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.'

PARAGRAPH 15**Supplementary information to Clause 15.4 – Representatives*****Amendment***

A new paragraph is added:

‘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.’

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PARAGRAPH 15**Supplementary information to Clause 15.3 General Medical Council*****Current text***

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

Amendment

Changed to:

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

The same change is made to the supplementary information to Clause 18.1 and the supplementary information to Clause 19.1.

CLAUSE 16**Clause 16.3 - Training*****Current text***

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

Amendment

'... must be entered for...' in the second sentence is changed to: '... must take...'

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Supplementary information to Clause 16.3 - Time allowed to pass examination***Current text***

The second and third paragraphs state:

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

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

Amendment

The second sentence of the second paragraph above is deleted. The first sentence of the second paragraph is retained.

An additional paragraph is added to go after the first paragraph above:

'Similarly, in the event of failure to take the examination within the first year, the Director may agree to the continued employment of a person as a representative, subject to the representative taking the examination within a reasonable time.'

CLAUSE 17

Clause 17 - Provision of medicines and samples

Amendment

A further clause is added (to be Clause 17.12)

'Samples must not be provided simply as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.'

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Supplementary information to Clause 17 - Definition of sample

Amendment

An additional paragraph is added:

'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.'

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Clause 17.2 - Provision of medicines and samples

Current text

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

Amendment

A further paragraph is added:

'Samples may not be provided of any medicine which has been on the UK market for more than ten years.'

CLAUSE 18**Supplementary information to Clause 18.1 Terms of trade*****Current text***

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

Amendment

Changed to:

'The Code of Ethics for Pharmacists and Pharmacy Technicians of the Royal Pharmaceutical Society of Great Britain states 'Do not ask for or accept gifts, inducements, hospitality or referrals that may affect, or be perceived to affect, your professional judgement.'

The supplementary information to Clause 20.1 [now Clause 22.1] is amended to give the new name of the Code of Ethics.

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Supplementary information to Clause 18.2 - Competitions and quizzes***Current text***

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

Amendment

A further paragraph is added:

'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.'

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Supplementary information to Clause 18.2 - Gifts to or for use by patients***Current text***

The third paragraph states:

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

Amendment

The title is changed to:

'Items given to or for use by patients.'

The third paragraph is changed to commence: 'No item for use by patients...'

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Clause 18.4 - Medical and educational goods and services

Current text

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

Amendment

Added to the supplementary information to Clause 18.4 is:

'The requirement in Clause 18.4 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.'

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Supplementary information to Clause 18.4 - Provision of medical and educational services

Current text

The supplementary information states, *inter alia*:

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

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

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

Amendment

A further paragraph is added:

'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.'

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ADDITION OF NEW CLAUSES 18.5 AND 18.6

Clause 18.5.

'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 (that are not otherwise covered by the Code) are only allowed if:

- they comply with Clause 18.4 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.'

Supplementary information to Clause 18.5:

'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 19. Companies are encouraged to make publicly available information about donations, grants or benefits in kind made by them which are covered by Clause 18.5. Companies are also encouraged to ask recipients to make such funding public.'

Clause 18.6

'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 18.4 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 19**Clause 19.1 – Meetings and hospitality*****Current text***

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

Amendment

The first sentence is changed to:

'Companies must not provide hospitality to members of the health professions and appropriate administrative staff except in association with scientific meetings, promotional meetings, scientific congresses and other such meetings, and training.'

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Supplementary information to Clause 19.1 - Meetings and hospitality***Current text***

The supplementary information states, *inter alia*:

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

Amendment

Changed to:

'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.'

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Supplementary information to Clause 19.1 - Meetings and hospitality***Current text***

The supplementary information states, *inter alia*:

‘With any meeting, certain basic principles apply:

- the venue must be appropriate and conducive to the main purpose of the meeting; lavish or deluxe venues must not be used and companies should avoid using venues that are renowned for their entertainment facilities.’

Amendment

Changed to:

‘...; 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...’

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Supplementary information to Clause 19.1 – Meetings and hospitality***Amendment***

Added to the supplementary information is:

‘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, excluding promotional aids, 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 authorised 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.’

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Clause 19.1 Meetings and hospitality

Amendment

A new section is added to the supplementary information:

'Clause 19.1 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.'

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Supplementary information to Clause 19.1 - Meetings and hospitality

Current text

The current text states, *inter alia*:

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

Amendment

Changed to:

'... other than to that referred to in Clauses 19.1 and 23.2 [new] and the supplementary information to Clauses 20 [new] and 20.2 [now 22.2].'

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Note

Clause 20 becomes Clause 22.

CLAUSE 21 [becomes Clause 24]**Clause 21.1 - The Internet [now Clause 24.1]*****Current text***

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

Amendment

Changed to:

'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.'

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Supplementary information to Clause 21.1 [now Clause 24.1] - Access***Current text***

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

Amendment

Changed to:

'Unless access to promotional material about prescription only medicines is limited to health professionals and appropriate administrative staff, a pharmaceutical company website or a company sponsored website must provide ...'

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Clause 21.3 – The Internet [now Clause 24.3]***Current text***

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

Amendment

Changed to:

'Information about medicines covered by Clauses 21.1 and 21.2 [now Clauses 24.1 and 24.2] above which is provided on the Internet and which is intended for members of the public must comply with Clause 20.2 [now Clause 22.2].'

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Clause 21.4 – The Internet [now Clause 24.4]

Current text

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

Amendment

The words 'Notwithstanding the provisions of Clauses 21.1 and 21.3 above' are deleted so that the clause starts 'A medicine covered by Clause 21.1 [now Clause 24.1] ...'.

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Note

Clause 22 becomes Clause 25.

NEW CLAUSE TO BE CLAUSE 13

A new clause is added to be titled:

'Non-interventional studies of marketed medicines'

The text to read:

Clause 13.1

'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.'

Clause 13.2

'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.'

Supplementary information to Clause 13.2:

'Companies are encouraged to comply with Clause 13.2 for all other types of studies covered by Clause 13.1, including epidemiological studies and registries and other studies that are retrospective in nature. In any case, such studies are subject to Clause 18.6.'

Supplementary information to Clause 13.2:

'Companies must begin to comply with Clause 13.2 in connection with any non-interventional studies that are completed after 1 July 2008, though companies are encouraged to do so prior to that date.'

Supplementary information to Clause 13:

'Companies are encouraged to 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.'

A cross reference to new Clause 13 is added to the supplementary information to Clause 10.2 [now Clause 12.2].

NEW CLAUSE TO BE CLAUSE 20

A new clause is added to be titled:

'The use of consultants'

Clause 20

'Health professionals 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 health professionals meet those criteria
- the number of health professionals 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 health professional 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.'

Supplementary information to Clause 20:

'In their written contracts with consultants, companies are strongly encouraged to 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 are strongly encouraged to 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.

Companies are strongly encouraged to include such provisions in any contracts entered into or renewed on or after 1 July 2008. In addition, 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 is excluded from the scope of Clause 20, provided that the health professional is 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 is minimal.

If a health professional attends an event in a consultant or advisory capacity the relevant provisions of Clause 19 apply.'

NEW CLAUSE TO BE CLAUSE 23***Amendment***

Clause 20.3 and its supplementary information are deleted in entirety.

A new clause is added to be titled:

'Relationships with patient organisations'.

Clause 23.1

'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.'

Supplementary information to Clause 23.1:

There are other codes and guidelines which cover patient groups, including Long-term Conditions Alliance guidelines and Charity Commission requirements etc.'

Clause 23.2

'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 23.8) and the prohibition on advertising prescription only medicines to the public (Clause 20.1 [now Clause 22.1]), The requirements of Clause 19, which covers meetings for health professionals and appropriate administrative staff, also apply to pharmaceutical companies supporting patient organisation meetings.'

Supplementary information to Clause 23.2:

'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 23.3

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.'

Supplementary information to Clause 23.3:

'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 23.4

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

Clause 23.5

'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.'

Supplementary information to Clause 23.5

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

Clause 23.6

'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.'

Clause 23.7

'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 short descriptions of the nature of the support. The list of organisations being given support must be updated at least once a year.'

Supplementary information to Clause 23.7

'The information required by Clause 23.7 must be made publicly available by no later than 31 March 2009 and must cover activities commenced on or after 1 January 2008 or ongoing on that date.'

Until the first such disclosure is made, the requirements for disclosure of all patient organisations to which a company provides financial support set out in the supplementary information to Clause 20.3 of the 2006 Code of Practice remain applicable.

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

Clause 23.8

'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.'

GENERAL POINT

Amendment

'general public' is replaced by 'public' whenever those words appear.

* * * * *

DATE OF IMPLEMENTATION

The following statement will appear at the front of the Code of Practice:

'This edition of the Code of Practice comes into operation on 1 July 2008. During the period 1 July 2008 to 31 October 2008, no promotional material or activity will be regarded as being in breach of the Code if it fails to comply with its provisions only because of requirements which this edition of the Code newly introduces.'

1 May 2008