

**AGREED AMENDMENTS
TO THE SECOND 2012 EDITION
ABPI CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY
AND ITS ADDENDUM**

CLAUSE 1 – SCOPE OF THE CODE AND DEFINITION OF CERTAIN TERMS

Amendment

Additional definition, Clause 1.8, added:

‘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.’

Supplementary information to new Clause 1.8 added:

‘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 19.1.’*

Current Clauses 1.8 and 1.9 renumbered.

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CLAUSE 4 – PRESCRIBING INFORMATION AND OTHER OBLIGATORY INFORMATION

Clause 4.11

Current text

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

Amendment

The words ‘special reporting’ changed to ‘additional monitoring’.

The word ‘equilateral’ added before ‘triangle’.

Similar changes made to Clause 5.7 relating to abbreviated advertisements.

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Clause 4.11 – Supplementary information

Current text

- *'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.'*

Amendment

New paragraph added:

'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.'

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CLAUSE 5 – ABBREVIATED ADVERTISEMENTS

Clause 5.4

Current text

Clause 5.4 states, *inter alia*:

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

- a statement that prescribers are recommended to consult the summary of product characteristics before prescribing, particularly in relation to side-effects, precautions and contra-indications
- the 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]'.

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

either, the information set out in Clauses 4.2 and 4.3 above (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),

or, the summary of product characteristics.

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.'

Amendment

The two stabpoints above replaced by:

'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 paragraph commencing 'either' and the final paragraph amalgamated to read:

'either, the information set out in Clauses 4.2 and 4.3 above (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),'

The words 'or the summary of product characteristics' remain.

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CLAUSE 9 – HIGH STANDARDS ETC

Clause 9.7

Current text

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

Amendment

The word 'promotional' deleted.

New paragraph added:

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

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

Material referred to in Clause 14.3 below must be certified by two persons one of whom must be a registered medical practitioner or, in the case of a product for dental use only, a registered medical practitioner or a dentist.

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

Amendment

'UK registered' added before 'dentist' in the first paragraph.

Second paragraph deleted.

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AMENDMENT NUMBER 7

CLAUSE 16 – TRAINING

Clause 16.3

Current text

Clause 16.3 states, *inter alia*,:

‘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.’

Amendment

New paragraph added:

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

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Clause 16.3

Current text

Clause 16.3 states, *inter alia*,:

‘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.’

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.’

Amendment

Added after the first paragraph above:

‘Such an examination must be a Diploma (at least 37 credits or equivalent learning hours)’.

Added after the second paragraph above:

‘Such an examination must be a Certificate (at least 13 credits or equivalent learning hours)’.

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Clause 16.3 – Supplementary information

Current text

The supplementary information to Clause 16.3 states, *inter alia*,:

‘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 such examinations are at least equivalent to those offered by the ABPI. The ABPI intends that its examinations will be accredited at least at Level 3 by an external awarding body recognised by Ofqual. Once this is achieved proposals will be made to amend the Code to require the examinations of all providers to be accredited at least at Level 3.'

Amendment

The second paragraph replaced with:

'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.'

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Clause 16.3 – Supplementary information

Amendment

Additional supplementary information added:

'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.'

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CLAUSE 17 – SAMPLES

Clause 17.2

Current text

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

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

Amendment

The word ‘new’ deleted in each paragraph.

New paragraph added:

‘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.’

Delete the supplementary information to Clause 17.2 relating to the definition of a new medicine.

Delete the supplementary information to Clause 17.2 relating to date of implementation.

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Clause 17.3

Current text

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

Amendment

Added:

‘An electronic signature is acceptable.’

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CLAUSE 18 – ITEMS FOR PATIENTS ETC

Clause 18.1 – Supplementary information

Current text

'A promotional aid is defined as a non-monetary gift made for a promotional purpose. Promotional aids may be given to health professionals and administrative staff 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 administrative staff must not be offered or provided.

Many items given as promotional aids in the past are no longer acceptable. These include coffee mugs, stationery, computer accessories such as memory sticks, diaries, calendars and the like.

Items for use with patients in the clinic, surgery or treatment room etc are also no longer acceptable. These include surgical gloves, nail brushes, tongue depressors, tissues and the like.

Items such as toys and puzzles intended for children to play with may no longer be provided.

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

Pharmaceutical companies can no longer 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. In the past these have sometimes carried advertisements for prescription medicines but this is now not acceptable. Advertisements for prescription medicines must not appear on any items 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 22 and its supplementary information. A story-book for young patients about a product or a disease could be provided for relevant patients.'

Amendment

Paragraphs 4, 5, 6, 7, and 8 replaced with:

'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.'

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Clause 18.3

Current text

'Health professionals and appropriate administrative staff attending scientific meetings and conferences, promotional meetings and other such meetings may be provided with inexpensive notebooks, pens and pencils for use at such 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.'

Amendment

Additional supplementary information to Clause 18.3 added:

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

'Notebooks, pens and pencils provided by one or more companies can be included in conference bags. The total cost of the items provided to an individual recipient must not exceed £6, excluding VAT. The perceived value to the recipient must be the same. The items may bear the names of the donor companies but not the name of any medicine or any information about medicines. No individual attendee should receive more than one notebook and one pen or pencil.'

The current wording of Clause 18.3 retained.

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Clause 18.5

Current text

'Joint working between one or more pharmaceutical companies and health authorities and trusts and the like 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.'

Amendment

New paragraph added:

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

Supplementary information to Clause 18.5 to read:

'Clause 18.5 Disclosure

The information required by Clause 18.5 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 21 below.'

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Clause 18.6 – Supplementary information

Current text

'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.

Details of each grant or donation must be 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.

The information required by Clause 18.6 must be made publicly available in respect of donations and grants made in 2012 and each calendar year thereafter. Disclosure must be in the calendar year following that in which donations and grants were provided and the information must be made public within three calendar months of the end of the company's financial year.

All reasonable steps should be taken by the local operating company to similar disclose donations and grants provided by overseas affiliates, head offices in the UK or overseas and UK based European offices.

Companies are encouraged to make publicly available information about benefits in kind provided by them which are covered by Clause 18.6.'

Amendment

'benefit in kind' added to 'donation or grant'.

Third paragraph replaced with:

'The information required by Clause 18.6 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 21 below.'

The fourth paragraph and final paragraph deleted.

The complete text is:

'Clause 18.6 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 19.

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 18.6 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 21 below.'

Added:

'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.'

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Clause 18.7

Current text

'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.'*

Amendment

A further paragraph added:

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

New supplementary information to Clause 18.7

'The information required by Clause 18.7 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 21 below.'

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CLAUSE 19 – MEETINGS, HOSPITALITY AND SPONSORSHIP

Amendment

New clause added, Clause 19.2:

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

Supplementary information to new Clause 19.2:

'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 19.1 and its supplementary information still apply.'

Current Clauses 19.2, 19.3 and 19.4 renumbered.

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Clause 19.4

Current text

'Pharmaceutical companies must make publicly available financial details of sponsorship of UK health professionals and appropriate administrative staff in relation to attendance at meetings organised by third parties. Sponsorship in this context includes registration fees, costs of accommodation (both inside and outside the UK) and travel outside the UK.'

Amendment

The words 'organised by third parties' deleted from the first sentence so that it states:

'Pharmaceutical companies must publicly disclose financial details of sponsorship of UK health professionals and appropriate administrative staff in relation to attendance at meetings.'

The second sentence replaced with:

'Sponsorship in this context includes registration fees and the costs of accommodation and travel, both inside and outside the UK.'

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Clause 19.4 – Supplementary information**Current text**

'Meetings at which attendance is sponsored by companies must comply with Clause 19.1. The information required by Clause 19.4 must be made publicly available in respect of sponsorship for attendance at meetings held in 2012 and each calendar year thereafter. Disclosure must be in the calendar year following that in which the payments were made and the information must be made public within three calendar months of the end of the company's financial year.'

The information which must be disclosed is the total amount paid in a calendar year in respect of all recipients and the total number of recipients. The total number of attendances at meetings sponsored in the year must also be given. The names of the recipients need not be disclosed.

Registration fees have to be included where the sponsorship of UK health professionals and appropriate administrative staff to attend meetings is paid by overseas affiliates, head offices in the UK or overseas and UK based European offices.

All reasonable steps should be taken by local operating companies to disclose their best estimates of the amounts for accommodation costs (both inside and outside the UK) and travel outside the UK for UK health professionals and appropriate administrative staff paid by overseas affiliates, head offices in the UK or overseas and UK based European offices.'

Amendment

The supplementary information replaced with:

'Disclosure of this information must be carried out in accordance with Clause 21 below.'

Meetings at which attendance is sponsored by companies must also comply with Clause 19.1.

The information required by Clause 19.4 must be made publicly available 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.'

Added:

'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.'

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CLAUSE 20 – THE USE OF CONSULTANTS

Clauses 20.2, 20.3 and 20.4

Current text

20.2 Pharmaceutical companies must make publicly available 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 does not include payments to consultants in relation to research and development work, including the conduct of clinical trials. Nor does it include payment of UK travel costs or the cost of subsistence in relation to fees for services which are dealt with in Clause 20.3.

20.3 In addition to the information required to be made public by Clause 20.2, companies must make publicly available 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) and payments in respect of accommodation (both in and outside the UK) and travel outside the UK in relation to fees for services as defined in Clause 20.2.

20.4 Fees, expenses and the like due to consultants in relation to Clauses 20.2 and 20.3 must be declared whether paid directly to them or to their employers or to companies or charities etc.'

Amendment

In Clause 20.2, the words 'It does not include ...' changed to 'It includes ...' and the final sentence deleted.

In Clause 20.3, the words '... and payments' to the end of the sentence replaced by:

'... and payments in respect of accommodation and travel (both inside and outside the UK).'

In Clause 20.4, the end of the sentence to read '... to them or to their employers or to healthcare organisations or to companies or charities etc.'

The complete text for Clauses 20.2, 20.3 and 20.4 is:

20.2 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.

20.3 In addition to the information required to be made public by Clause 20.2, 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).

20.4 Fees, expenses and the like due to consultants in relation to Clauses 20.2 and 20.3 must be disclosed whether paid directly to them or to their employers or to healthcare organisations or to companies or charities etc.'

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Clauses 20.2 and 20.3 – Supplementary information

Current text

'Clause 20.2 Disclosure

The information required by Clause 20.2 must be publicly disclosed in respect of payments made to UK consultants in 2012 and each calendar year thereafter. Disclosure must be in the calendar year following that in which the payments were made and the information must be made public within three calendar months of the end of the company's financial year.

The information which must be disclosed is the total amount paid in a calendar year to all of the consultants who have provided services. The total number of consultants must be given. The names of the consultants need not be disclosed. Companies may, of course, give greater detail, for example, by giving separate figures for different categories of service or by providing details of the maximum and minimum payments etc.

All reasonable steps should be taken by local operating companies to similarly disclose their best estimates of fees paid to UK consultants by overseas affiliates, head offices in the UK or overseas and UK based European offices.

Clause 20.3 Disclosure

Clause 20.3 relates only to market research using consultants whose identity is known to the pharmaceutical company. 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. The names of the consultants need not be disclosed.

The information required by Clause 20.3 in respect of payments made to UK consultants in 2013 and each calendar year thereafter must be made publicly available by including it in the fees for service declaration required by Clause 20.2 and its supplementary information.'

Amendment

Amended to read:

'Clause 20.2 Disclosure

The information required by Clause 20.2 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 21 below.

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 20.2 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 20.3 Disclosure

Clause 20.3 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.

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.'

NEW CLAUSE 21 – TRANSFERS OF VALUE TO HEALTH PROFESSIONALS AND HEALTHCARE ORGANISATIONS

Amendment

New clause added, Clause 21:

'Clause 21

Transfers of Value to Health Professionals and Healthcare Organisations

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

21.2 The transfers of value covered by Clause 21.1 are:

- joint working in accordance with Clause 18.5
- donations, grants and benefits in kind provided to institutions, organisations and associations in accordance with Clause 18.6
- contracts between companies and institutions, organisations and associations in accordance with Clause 18.7
- sponsorship of attendance by health professionals at meetings in accordance with Clause 19.5
- fees paid to health professionals and appropriate administrative staff, or to their employers on their behalf, in accordance with Clauses 20.2 and 20.3
- contributions towards the cost 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.

21.3 Clause 21.1 does not apply to transfers of value to patient organisations. These transfers of value are covered by Clauses 24.7 and 24.8. [Note: Currently Clauses 23.7 and 23.8]

21.4 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.

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

21.6 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.

21.7 Different categories of transfers of value 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.

21.8 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.

21.9 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.

21.10 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.

Supplementary information to Clause 21

‘Clause 21.1 Transfer of Value

The term ‘transfer of value’ is defined in Clause 1.8 above. [A new clause]

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

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 21.1 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 disclose. Companies must ensure that they have appropriate arrangements in place to lawfully disclose information about transfers of value.

Clause 21.1 Mode of Disclosure

Disclosure will be on the company’s website but, if a central platform for disclosure in the UK is established, the use of that platform is likely to be obligatory.

The decision as to whether there will be a central platform for disclosure in the UK will be made by the end of 2014.

A template which can be used is available to download from the Authority’s website (www.pmcpa.org.uk).

Clause 21.1 Date of Implementation

The information required by Clause 21.1 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 21.2 Further Information

The clauses of the Code noted in Clause 21.2 should be consulted for further information about the requirements. In addition, the requirements of Clauses 19.1 and 19.4 should be borne in mind in relation to sponsorship of meetings.'

Current Clauses 21, 22, 23, 24 and 25 renumbered.

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CLAUSE 21 – SCIENTIFIC SERVICES

Clause 21.2

Current text

'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.'

Amendment

The words 'where appropriate' before 'a pharmacist' deleted and 'registered in the UK' added after pharmacist.

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Clause 21.3

Current text

'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.'

The supplementary to Clause 21.3 states:

'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 2009 and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature 2010, both at <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.'

Amendment

Clause 21.3 and its supplementary information transferred from Clause 21 to Clause 13 (to be Clause 13.1) retitled:

'Clinical Trials and Non-Interventional Studies of Marketed Medicines'.

Existing Clauses 13.1, 13.2 and 13.3 renumbered as Clauses 13.2, 13.3 and 13.4.

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Clause 21.3 – Supplementary information

Amendment

A further paragraph, to be the second paragraph, added:

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

Clause 21.3 now Clause 13.1.

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CLAUSE 22 – RELATIONS WITH THE PUBLIC AND THE MEDIA

New clause

Amendment

A new clause, Clause 22.3, added:

'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 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”.

Supplementary information to Clause 22.3:

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

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.

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CLAUSE 23 – RELATIONSHIPS WITH PATIENT ORGANISATIONS

Clauses 23.7 and 23.8

Amendment

Supplementary information to Clauses 23.7 and 23.8 added:

‘Clauses 23.7 and 23.8 Transfers of Value to Patient Organisations

Transfers of value to patient organisations made in accordance with Clauses 23.7 and 23.8 are not subject to the requirements relating to transfers of value set out in Clause 21. Clause 21.3 excludes them from its scope.’

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Clauses 23.7 and 23.8 – Supplementary information

Current text

‘Clause 23.7 Date of Implementation

A list of patient organisations including the monetary value of support regardless of its level must be made publicly available by the end of the first quarter of 2013 and cover activities commenced on or after 1 January 2012 or ongoing on that date.

Until that information is made publicly available, the requirements for disclosure set out in Clause 23.7 of the 2011 Code of Practice and its supplementary information remain applicable.

Clause 23.8 Date of Implementation

A list of patient organisations that have been engaged to provide significant contracted services must be published for the first time by the end of the first quarter of 2013 and cover activities commenced on or after 1 January 2012 or ongoing on that date.'

Amendment

Both items of supplementary information deleted.

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GENERAL

Amendment

- a) All references to 'side-effect' changed to 'adverse reaction'.
- b) All references to 'package information leaflet' and the like changed to 'package leaflet'.

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GENERAL

Amendment

Names of organisations, titles of publications and similar factual matters in the Code of Practice booklet have been updated.

At a few points in the Code references are made to health authorities, trusts, NHS trusts, health boards, primary care organisations and the like. Some of these bodies no longer exist and the matter is complicated by differing nomenclature in the four home countries. Such references have been simplified.

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Amendment

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 2014. During the period 1 January 2014 to 30 April 2014, no promotional material or activity will be regarded as being in breach of the Code if its fails to comply with its provisions only because of requirements which this edition of the Code newly introduces.'

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Various clauses including 14 and 21.

Amendment

References to 'pharmacist' or 'UK registered pharmacist' changed to pharmacist registered in the UK.

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Clause 18.1 – Supplementary information DVDs and memory sticks

Current text

'... provision ... of DVDs etc that bear ...'.

'... provision ... of memory sticks that bear ...'.

Amendment

'inexpensive' added before 'DVDs etc' and 'memory sticks'.

5 November 2013