PMCPA | Prescription Medicines Code of Practice Authority

Main changes to the ABPI Code of Practice for the Pharmaceutical Industry and to the PMCPA Constitution and Procedure

Changes to the 2015 Code

- Agreed by ABPI Members 11 November and 1 December 2015
- To come into operation on 1 January 2016

Changes due to:

- The move from aggregate disclosure to individual disclosure
- Implementation of the EFPIA Disclosure Code
- Withdrawal of the unaccredited ABPI representative's examination
- Outcome of ABPI Board Review
- Regular updating/tidying up

2016 Code

Operative on 1 January 2016.

Transition period until 30 April 2016 to comply with newly introduced provisions.

Main changes Clause 1 Scope and Definitions

Clause 1.1 Supplementary Information – Joint Working

Amendment

Cross-refer to Clause 20 supplementary information and delete repetition.

New text

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

Main changes Clause 1 Scope and Definitions

Clause 1.10

Amendment

Disclosure linked to when the company knows or can identify the recipient rather than when the recipient can identify the company.

New text

‘The term “transfer of value” means a direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines. A direct transfer of value is one made directly by a company for the benefit of a recipient. An indirect transfer of value is one made on behalf of a company for the benefit of a recipient or through an intermediate and where the company knows or can identify the recipient that will benefit from the transfer of value.’

Main changes Clause 4 Prescribing Information and Other Obligatory Information

Clause 4.2

Amendment

New supplementary information added to explain the use of the summary of product characteristics (SPC) as a means of providing information required in Clause 4.2 i-viii in certain situations.

New text

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

The Code defines prescribing information to consist of three parts, the legal classification, the cost and other elements (listed as i-viii) in Clause 4.2. In certain situations elements i-viii can be provided by the summary of product characteristics.

cont….

Main changes Clause 4 Prescribing Information and Other Obligatory Information

cont …

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

Main changes Clause 4 Prescribing Information and Other Obligatory Information

Clause 4.8

Amendment

Deleted Clause 4.8 ‘In the case of printed promotional material consisting of more than four pages, a clear reference must be given to where the prescribing information can be found’ as there is no longer a requirement to include a reference to where the prescribing information can be found.

Clauses 4.9, 4.10 and 4.11 renumbered.

Main changes Clause 11 Distribution of Promotional Material

Clause 11.1 Supplementary Information – Distribution of Promotional Material

Amendment

Removed two references to ‘promotional’. As all material should be tailored to the audience to whom it is directed.

New text

‘***Clause 11.1 Supplementary Information – Distribution of Material***

Material should be tailored to the audience to whom it is directed. For example, promotional material devised for general practitioners might not be appropriate for hospital doctors and, similarly, material devised for clinicians might not be appropriate for use with other relevant decision makers.’

Main changes Clause 14 Certification

Clause 14.1

Amendment

Reworded to reflect that only one signatory is required for certification. The signatory must be either a registered medical practitioner or a pharmacist registered in the UK and must not be responsible for developing or drawing up the material.

Consequential changes to Clause 14.5 and the supplementary information to Clause 14.1.

Cont …

Main changes Clause 14 Certification

New text

Clause 14.1 to read:

‘**Clause 14 Certification**

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

The person certifying on behalf of the company must not be the person responsible for developing or drawing up the material.’

Main changes Clause 14 Certification

Clause 14.1 Supplementary Information – Joint Ventures and Co-Promotion

Amendment

Replaced '*two final signatories*' and '*signatories*' with '*one final signatory*' and '*signatory*'.

New text

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

Main changes Clause 14 Certification

Clause 14 Certification

Clause 14.2

Amendment

Replaced current requirement to certify all meetings which involve travel outside the UK with a requirement to certify certain meetings.

Current exemption when companies only involvement is to support a speaker moved to the supplementary information.

New text

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

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

Main changes Clause 14 Certification

Clause 14.2 Supplementary Information

Amendments

Made clear that the responsibility under the Code for meetings attended by UK delegates/speakers is with the UK company.

'*Certified*' replaced with '*examined by the UK company*' in certain situations.

If overseas companies invite UK delegates to a meeting which is not wholly or mainly for UK delegates then the UK company must be informed and the arrangements examined by the UK company.

New paragraph added regarding the nature of meetings when certification or examination are not required.

Main changes Clause 14 Certification

Clause 14.2 Supplementary Information – Meetings Involving Travel Outside the UK

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

When certifying arrangements for meetings which involve travel outside the UK all the relevant documents and arrangements must be considered including the programme, the venue, the reasons for using that venue, the intended audience, the anticipated cost and the nature of the hospitality and the like.

cont …

Main changes Clause 14 Certification

Clause 14.2 Supplementary Information – Meetings Involving Travel Outside the UK

cont …

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

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

cont …

Main changes Clause 14 Certification

Clause 14.2 Supplementary Information – Meetings Involving Travel Outside the UK

cont …

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

Main changes Clause 14 Certification

Clause 14.2 Supplementary Information

Amendment

New supplementary information added.

New text

'Clause 14.2 Presentations by UK Speakers at Meetings Held Outside the UK

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

Main changes Clause 14 Certification

Clause 14.5

Amendment

Paragraphs 1, 2 and 4 changed from signatories to signatory regarding meetings involving travel outside the UK deleted, covered in Clause 14.2.

Main changes Clause 14 Certification

Clause 14.1

Amendment

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

New text

‘The names of those nominated as signatories as set out in Clause 14.1, together with their qualifications, shall be notified in advance to the Advertising Standards Unit, Vigilance and Risk Management of Medicines of the Medicines and Healthcare products Regulatory Agency and to the Prescription Medicines Code of Practice Authority. The names and qualifications of designated alternative signatories must also be given. Changes in the names of nominees must be promptly notified.’

Main changes Clause 15 Representatives

Clause 15.3 Supplementary Information – Health Professionals' Codes of Conduct

Amendment

Three paragraphs combined, simplified and a cross-reference added.

New text

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

Main changes Clause 16 Training

Clause 16.3 Supplementary Information – Introduction of Accredited Examinations

Amendment

Reworded to reflect the withdrawal of the unaccredited examination on 31 December 2015.

New text

'Clause 16.3 Accredited Examinations

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

cont…

Main changes Clause 16 Training

cont …

The unaccredited examination ceased on 31 December 2015 therefore a candidate who has passed part of an unaccredited ABPI examination but did not complete it by 31 December 2015 will have to transfer to an accredited examination. The limitations on time within which representatives must pass an examination, which are set out in Clause 16.3 and its supplementary information, must be borne in mind.'

Main changes Clause 17 Provision of Medicines and Samples

Amendment

Clauses 17.7 and 17.8 deleted and moved to a new second paragraph in the existing supplementary information to Clause 17.9 Control and Accountability.

Clauses 17.9, 17.10, 17.11 and 17.12 re-numbered

New text

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

Main changes Clause 18 Prohibition on Inducements etc

Clause 18.1 Supplementary Information – Promotional Aids

Amendment

Deleted *'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.'*

Remaining text

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

Main changes Clause 19 Medical and Educational Goods and Services (MEGs)

Clause 19.1 Supplementary Information

Amendment

Deleted *'by the Code of Practice signatories within companies to ensure that the requirements of the Code are met' from point 8*.

Remaining text

'Material relating to the provision of medical and educational goods and services, such as internal instructions, external instructions, the written protocol for recipients and other material, including material relating to therapy reviews, etc, must be certified as required by Clause 14.3.'

Main changes Clause 20 Joint Working

Clause 20 Supplementary information

Amendment

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

New text

'Attention is drawn to the certification requirements set out in Clause 14.3 which apply to material relating to joint working including the project initiation documentation and the executive summary of the joint working agreement. Only the final documents etc for any joint working project need to be certified. All documents etc used during the development of the project should be of the same standard as certified material but there is no requirement to certify such materials. The joint working agreement does not need to be certified.'

Main changes Clause 23 The Use of Consultants

Clause 23 Supplementary Information – The Use of Consultants

Amendment

References to renegotiating existing contracts and to the exemption for limited market research deleted.

Remaining text

'The requirement that contracts or agreements with consultants must include provisions regarding their obligation to declare the arrangement whenever they write or speak in public applies to contracts entered into a renewed on or after 1 May 2011.'

Main changes Clause 24 Transfers of Value etc

Clause 24.9 Supplementary Information – Aggregate disclosure

Amendment

New supplementary information added regarding individual disclosure.

New text

'Clause 24.9 Supplementary Information – Aggregate disclosure

Disclosure of transfers of value to individuals

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

Main changes Clause 26 Relationships with the Public and Media

Amendment

Deleted Clause 26.5 ‘The introduction of new medicine must not be made known to the public until reasonable steps have been taken to inform the medical and pharmaceutical professions of its availability.’

Clause 26.6 re-numbered.

Main changes Clause 27 Relationships with Patient Organisations

Clause 27.3 Supplementary information – Written agreements

Amendment

Text changed to make it clearer that written agreements need to be certified

Current text (extract)

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

New replacement text

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

Main changes Clause 27 Relationships with Patient Organisations

Amendment

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

New text

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

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

GENERAL

- All references to disclosures in relation to the calendar years 2013 and 2014 have been deleted (Clause 19, 22, 23, and 24.1 supplementary information).
- Names of organisations, titles of publications and similar factual matters in the Code of Practice booklet updated.

Main changes Constitution and Procedure

Paragraph 3 Code of Practice Appeal Board – Constitution

Amendment

Deleted arrangements for members appointed prior to 1 January 2006.

Main changes Constitution and Procedure

Paragraph 7.1 Code of Practice Panel Rulings

Amendment

References to ‘promotional’ material in relation to rulings and the provision of an undertaking deleted.

Transition provisions

‘This edition of the Code of Practice comes into operation on 1 January 2016. During the period 1 January 2016 to 30 April 2016, no material or activity will be regarded as being in breach of the Code if it fails to comply with its provisions only because of requirements which this edition of the Code newly introduces.’