

The 2008 ABPI Code of Practice **written agreements and their certification**

The ABPI Code of Practice for the Pharmaceutical Industry governs pharmaceutical companies in their relationships with health professionals, the public and patient organisations. The Prescription Medicines Code of Practice Authority (PMCPA), administers the Code at arm's length from the ABPI. A copy can be found at www.pmcpa.org.uk.

The 2008 ABPI Code includes Clause 23, Relationships with Patient Organisations which expands the requirements in the previous edition of the ABPI Code. The ABPI Code applies to activities in the UK and activities outside the UK undertaken by a UK pharmaceutical company.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations is implemented in the UK by the 2008 ABPI Code. The ABPI Code reflects and extends beyond this EFPIA Code.

This document is based on the 2008 ABPI Code.

Pharmaceutical companies must make public by means of information on their websites or in their annual report a list of all patient organisations to which they provide financial support and/or significant indirect/non-financial support and must include short descriptions of the nature of that support. The list must be updated at least once a year (Clause 23.7).

Written agreements

Pharmaceutical companies working with patient organisations must have in place a written agreement setting out exactly what has been agreed, including funding, for every significant activity or ongoing relationship (Clause 23.3). This would include core funding and unrestricted grants, where the funder has no say or involvement in how that money is used, ie a completely arm's length arrangement.

The written agreement for sponsored/partnership activities is intended as a straightforward record of what has been agreed, taking into account the requirements of the ABPI Code. The level of detail should reflect the complexity and duration of the activity.

In addition, it might be advisable, either as part of this agreement or, more likely, as a separate document, for all parties involved to agree operational details of a project that they could refer back to as work progresses or draws to a close. Clarity is important, particularly in lengthy projects where there may be changes to personnel working on projects, their line managers or to boards of trustees.

The written agreement between the pharmaceutical company and patient organisation must be certified in accordance with Clause 14.3 of the Code and include the following details as set out in the supplementary information to Clause 23.3 of the Code. These being:

- the name of the activity
- names of the organisations involved (pharmaceutical company, patient organisations or similar and any third parties which will be brought in to help)
- the type of activity (eg unrestricted grant, specific meeting, publication etc)
- the objectives

- the respective roles of the company and the patient organisation
- the timeframe
- the amount of funding
- a description of significant indirect/non-financial support (eg the donation of public relations agency time, 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 that will apply
- the signatories to the agreement
- the date of the agreement.

In addition to the above it is advisable if the written agreement refers to certification of the output of the project (in the case of a pharmaceutical company, Clause 14) or examination in accordance with the appropriate internal approval procedures.

Certification

Certification is the way in which materials are approved by a pharmaceutical company before use. All promotional material and much non promotional material has to be certified in its final form to which no subsequent amendments are made by two experienced, appropriately qualified people. One of the signatories has to be a registered medical practitioner or, in certain limited circumstances, a pharmacist. The signatories examine the material and certify that in their belief it is in accordance with the Code and relevant advertising regulations (UK law), is not inconsistent with the marketing authorization and the summary of product characteristics and is a fair and truthful presentation of the facts about the medicine.

The PMCPA and the Medicines and Healthcare products Regulatory Agency (MHRA) have to be notified in advance the names and qualifications of the signatories.

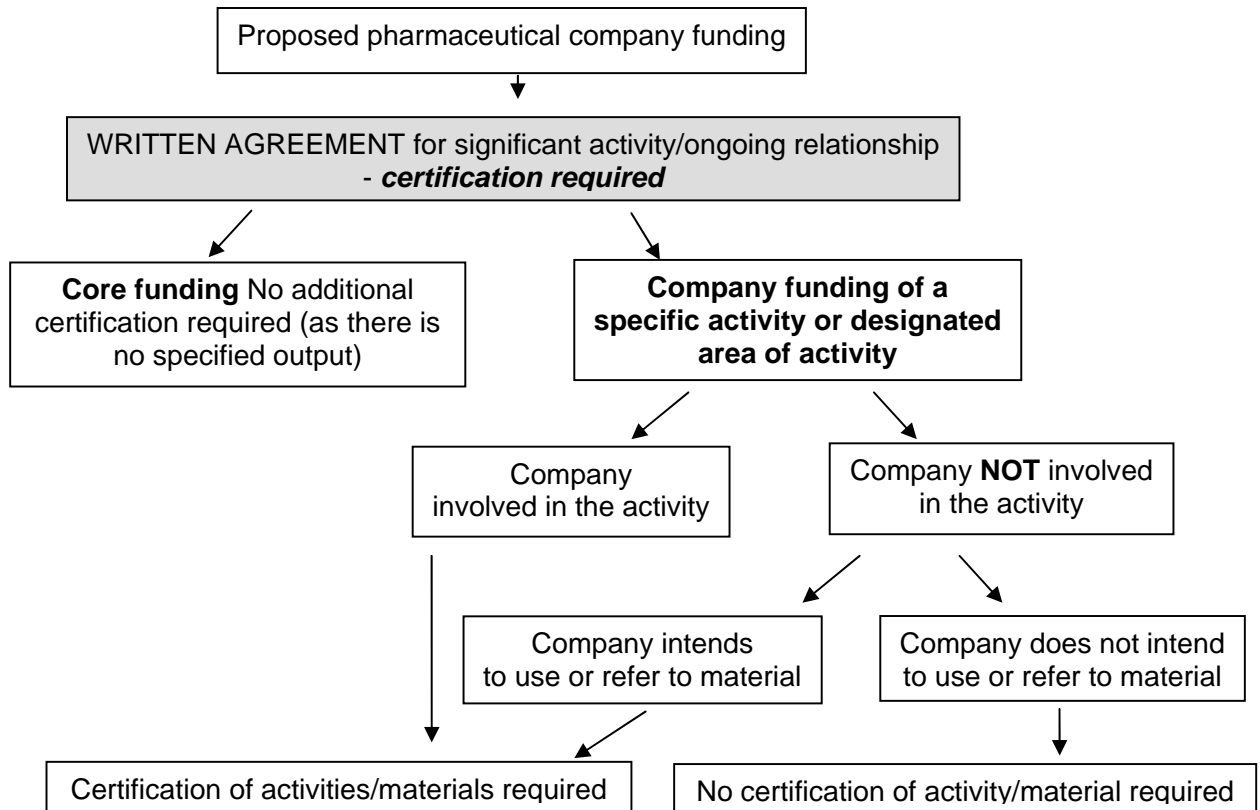
The written agreement itself must be certified. In addition the output of sponsored/joint activities will, in most cases, also need to be certified. Clause 14.3 refers to the need to certify educational material for the public or patients issued by companies which relates to diseases or medicines but is not intended as promotion for those medicines including material relating to working with patient organisations. When such material is certified, one of the two signatories must be a registered medical practitioner. Any material that a company has had a meaningful opportunity to influence the content of which mentions medicines or diseases, or which the company intends to distribute, must be certified.

It is important that all partners understand a company's obligations under the Code and in particular certification. A company's need to certify the final form before use should not be misinterpreted as a desire to control, rather it is a formal statement that the signatories consider that the material complies with the Code, relevant advertising law etc as outlined above.

At the same time as meeting the certification requirements of the Code, a company needs to be sensitive to patient organisations' expertise so that changes are kept to a minimum.

The pharmaceutical company and patient organisation need to agree a timetable for certification and build it into project deadlines.

Certification requirements for pharmaceutical industry funding of patient group activities



NB Arrangements for pharmaceutical meetings held outside the UK must be certified and all funded meetings must comply with Clause 19 of the ABPI Code irrespective of whether the pharmaceutical company is involved. (See Clauses 14 and 22 and their supplementary information for detailed guidance).