PMCPA | Prescription Medicines Code of Practice Authority

# GUIDANCE ABOUT CERTIFICATION

## INCLUDING CERTIFICATION OF MULTI COMPANY PROJECTS



This guidance on certification examines in particular the requirements in relation to projects involving a number of companies and reflects the requirements of the 2016 Code.

There appears to be confusion regarding what needs to be certified, particularly in relation to multi company projects, and/or joint working projects and how this can best be achieved. It is important to remember that the ABPI Code of Practice for the Pharmaceutical Industry covers promotional and non-promotional materials and activities.

The PMCPA cannot approve any materials or activities, it can only give informal advice based on its interpretation of the Code. In the event of a complaint being received about a matter upon which advice had been sought, it would be considered in the usual way; the Code of Practice Appeal Board would make the final decision if a case went to appeal.

## A BACKGROUND AND GENERAL COMMENTS

Certification requirements were introduced to the Code over 40 years ago as a means of ensuring that the final form of material, to which no subsequent amendments would be made, was examined carefully before being used. Certification has worked well and provides reassurance, particularly to those outside the industry, that companies cannot issue materials unless they have been appropriately approved. Pharmaceutical companies need to be confident that material meets the requirements of the Code. Clause 14.5 requires companies to certify that promotional material is in accordance with relevant advertising regulations, the ABPI Code and is not inconsistent with the marketing authorization and the summary of product characteristics (SPC). Over the years certain non-promotional activities and materials have been added to the requirements for certification.

In 2016 the requirements changed such as to allow just one final signatory to certify material, instead of it having to be two.

The supplementary information to Clause 14.3, Examination of Other Material, encourages experts on the Code to examine certain non-promotional material to ensure that it does not contravene the Code or the relevant statutory requirements.

A key requirement of certification is that signatories have all the pertinent information including how material is to be used. This is particularly important if the material is non-promotional. Certifiers need to be certain that such material is not being used for a promotional purpose.

The guidelines on company procedures relating to the Code of Practice (published at the back of the Code of Practice booklet) give helpful information about the process. It is important that all relevant materials are certified and that if an advertisement appears in two or more sizes or layouts each must be separately certified.

Companies' own policies and procedures are often more restrictive than the Code. There are examples where the arrangements for certification in a company go further than the requirements of Clause 14. For example the supplementary information to Clause 22.1, Certification of Meetings, states that companies must ensure that all meetings are checked to see that they comply with the Code and that companies must have a written document that sets out their policies on meetings and hospitality and the associated allowable expenditure. In addition, certain meetings which involve travel outside the UK must be formally certified as set out in Clause 14.2. Clause 14.2 of the Code states that all meetings involving travel outside the UK where a UK company funds UK delegates must be certified in advance. The supplementary information to Clause 14.2 sets out limited exceptions regarding certification and this should be consulted for details. Whether meetings require certification or not, companies are reminded that they nonetheless have responsibilities under the Code for meetings which they organise and when UK delegates and/or speakers are invited or supported to go to meetings outside the UK. Clauses 23 and 24 in relation to transfers of value also need to be followed.

Certification is often the final step in a process that involves review by a range of staff prior to final approval. The Code requires that the final form of promotional material is certified by a nominated signatory who must be either a registered medical practitioner or a pharmacist registered in the UK. If the product is only for dental use then a UK registered dentist can certify promotional material instead of the pharmacist or medical practitioner. The person certifying on behalf of the company must not also be responsible for developing or drawing up the material. The PMCPA and the Medicines and Healthcare products Regulatory Agency (MHRA) must be notified in advance of the names and qualifications of signatories.

Companies may use validated electronic signatures for certifying the final form of material. Paper or electronic copies of certificates and the final form of material etc must be preserved in order to comply with Clause 14.6.

If the final form of the item is to be printed companies can certify the final electronic version to which no subsequent amendments will be made. When such material is printed the company must ensure that the printed material cannot be used until one of the company's signatories (ie a registered medical practitioner or a pharmacist registered in the UK) has checked and signed the item in its final form. In such circumstances the material will have two certificates and both must be preserved.

In relation to certifying material on databases, interactive systems and the Internet, companies must ensure that a written transcript of the material is certified including reproductions of any graphs, tables and the like that appear in it. In the event of a complaint, a copy of the written material will be requested. Alternatively, companies may certify material on interactive systems by means of producing an electronic copy, for example, on a CD ROM or data stick if the electronic copy is write protected and unable to be changed.

When certifying dynamic content for websites care must be taken to ensure the dynamic content meets the requirements of the Code both as a standalone item and within the context it appears. The final form of digital material might not be static.

There are also requirements in Clause 14.6 about how long materials and certificates should be kept.

## B WHAT NEEDS TO BE CERTIFIED?

This is set out in Clauses 14.1, 14.2 and 14.3.

1 Promotional material.
2 All meetings involving travel outside the UK that are wholly or mainly for UK delegates or where the UK company funds UK delegates to attend.
3 Educational material for the public or patients that relates to disease or medicines.
4 Material relating to working with patient organisations as described in Clause 27 and its supplementary information.
5 Material relating to joint working as described in Clause 20 and it's supplementary information.
6 Material relating to patient support programmes as described in Clause 18.2 and its supplementary information.
7 Non-promotional material for patients or health professionals relating to the provision of medical and educational goods and services as described in Clause 19.1 and paragraph 8 of its supplementary information.

## C JOINT VENTURES AND CO-PROMOTION

The supplementary information to Clause 14.1, Joint Ventures and Co-Promotion, makes it clear that under co-promotion arrangements, whereby companies jointly promote the same medicines and the promotional material bears both company names, each company will be held jointly responsible for it under the Code.

In some instances where two companies are both promoting the same product the companies can agree beforehand to have only one final signatory to certify on behalf of both companies. The PMCPA and MHRA must be informed in advance who the signatory will be.

## D MULTI COMPANY PROJECTS – INCLUDING MULTI COMPANY JOINT WORKING PROJECTS

These are often quite detailed projects and project management is very important. The project plan should set out the responsibilities for each company in relation to ensuring that the arrangements and materials meet the requirements of the Code. Before finalising the project plan each company should be confident that any Code issues have been resolved. Often it is the way that activities are done that leads to problems rather than the project aim. With good planning, including early involvement of the appropriate personnel, final certification can be relatively straightforward.

As with joint ventures and co-promotion above, the companies can agree to have only one final signatory to certify on behalf of all the companies. The arrangements for certification should be clear and agreed at the outset.

If the companies decide to have only one final signatory for the project, rather than each company certifying the material, then as in Point C above, the arrangements must be agreed beforehand and the PMCPA and MHRA informed in advance who the signatory will be.

If a complaint were received about a multi company project then all the companies would be responsible under the Code. Similarly if a complaint were received about a project run by an ABPI therapy group then all the members would be contacted and would be responsible under the Code.

## E HOW TO HELP THOSE CERTIFYING JOINT WORKING PROJECTS

It is important that all staff in a position to identify a joint working opportunity are aware of the definition of such projects. A true joint working project is defined by the Department of Health (and detailed in the supplementary information to Clause 20).

Is it a joint working project or is it something else such as a medical or educational good or service (MEGS) (Clauses 19 and 21)?

The following may be useful questions to ask in relation to joint working but may apply more widely:

1 Are staff drawing up joint working projects familiar with the Code requirements and other relevant documents including company policies and procedures?
2 For each project, is all the documentation clear about each party's role and contribution to the project?
3 Have company compliance experts and signatories been involved in the projects right from the start and throughout their development?
4 Has sufficient time been allowed for approval?
5 Are the materials put into the system capable of being approved? Does the material and suggested activity comply with the Code? Is it in line with company policies? Is it grammatically correct?
6 Does the project plan cover certification arrangements?
7 Are records of meetings and agreed actions kept and meeting outcomes followed up?
8 Are the relevant personnel attending meetings?

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