Compliance, Codes and Communications

A practical guide to pharmaceutical marketing in the UK

Fifth edition: Covering the 2016 ABPI Code

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CHAPTER 2

Meetings and Congresses

Main clauses: 10, 12, 22, 23

Both promotional and non-promotional meetings are covered under the scope of the ABPI Code of Practice:

- Promotional (e.g. sales-representative organised meetings);
- Non-promotional (e.g. non-product educational meetings, advisory boards and investigator meetings for clinical studies).

The 2016 Code has clarified when the arrangements for meetings involving travel outside the UK require certification or examination. Refer to **Chapter 1: Basic Principles – Certification and examination** for details.

Corporate hospitality which is not associated with an allowable event should not be provided to healthcare professionals, patient groups etc., although it can be given and received as part of normal business activities that fall outside the scope of the Code, e.g. relationships with vendors, such as those providing computer services.

Congresses are meetings that are organised independently rather than by pharmaceutical companies, although companies will often sponsor them. International congresses are usually held in a different country each year and are intended for an international audience. National meetings of organisations are usually intended mainly for an audience from a particular country. The difference between international congresses and national congresses is important and will be discussed further in the relevant sections.

Promotional meetings Clauses 10, 12, 18, 22, 23

Company-organised promotional meetings are allowed but the ABPI requires that the company's involvement in the meeting is transparent. The primary purpose of the meeting must be its educational content. It is useful to state the educational aims in the invitation and these must be met. Note that a meeting may be highly scientific and may provide good quality educational content but it can still be promotional. The judgements on promotional versus non-promotional, and scientific and educational versus non-scientific are separate albeit related.

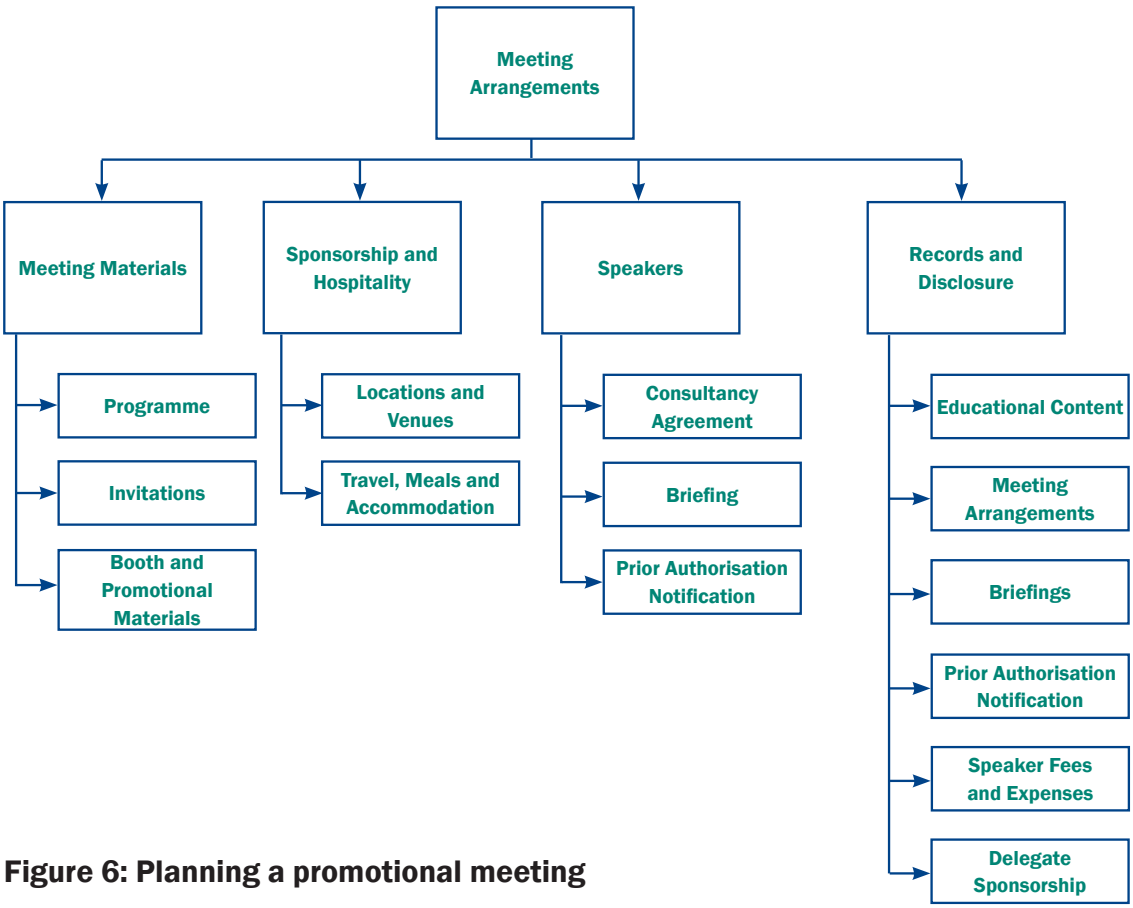

Figure 6: Planning a promotional meeting

Learning from a Case: Auth/2331/7/10 – Educational presentation in promotional meeting

An invitation was sent by a pharmaceutical company with a covering letter which clearly described a meeting as promotional and sponsored by a pharmaceutical company. An educational presentation given at the meeting focused on an off-label indication of the product concerned. The Panel ruled that both recipients of the invitation and delegates would inevitably associate the product with this off-label indication and that this presentation made the promotion of the product inconsistent with its licence.

Learning Point:

- **Don't try to integrate promotional and non-promotional meetings.**

Examples of promotional meetings include:

- Sales-representative organised lunchtime and evening meetings, e.g. local meeting for GPs or hospital departments;
- Large national product launch meetings;
- 'Roadshows' product launch or new-indication promotional meetings held at various venues around the country.

Hints & Tips
For any hospitality think IMPRESSION, IMPRESSION, IMPRESSION. If this meeting is made public, for example if it appears in the press or a competitor finds out, will your company (and the MHRA and PMCPA) be happy with the impression it creates????

There may or may not be a company stand or booth at the meeting. This may range from a small table-top stand to a large walk-on structure with advertising panels. All promotional material must meet the requirements of the ABPI Code.

Impression

The first and last thing to think about when organising a meeting is the IMPRESSION that is going to be created. Ask yourself the following questions:

- If the details of this meeting were to be described fairly in the tabloid press what impression would it give?
- Would you, your company, the regulators and self-regulatory bodies be happy with the impression created?

If the answers are that the details of the meeting would give a bad impression then the arrangements are not compliant and should be changed.

Meeting materials

Numerous types of materials are associated with a promotional meeting, for example:

- Programme;
- Invitations and welcome letters;
- Booth panels and other promotional materials;
- Powerpoint presentations and videos;
- Presentation notes and handouts for delegates;
- Post-meeting report.

All materials must be consistent with the licence and meet the requirements of the ABPI Code, they must be reviewed and individually certified as standalone items. Refer to **Chapter 3: Printed Materials – Tables 7, 8 and 9** for details of requirements Additionally all materials must make it clear that it is a company-organised meeting.

N.B. The company is also responsible for any materials produced by third parties, e.g. welcome letters from the conference organiser. These must all comply with the Code and be approved by the pharmaceutical company.

Hints & Tips
Document the educational purpose when starting to plan the meeting and make this clear in the invitations.

Companies must make the financial details of consultancy fees paid to UK health professionals and other relevant decision makers publicly available. Refer to **Table 1: Summary of requirements when disclosing transfers of value to HCPs and HCOs** for further information.

Arrangements

The arrangements for company satellite symposia must comply with certain conditions in order for them to be seen as suitable vehicles for the 'exchange of legitimate scientific information' and not be classed as promotional meetings. Company satellite symposia should be arranged as part of the official congress programme as opposed to being arranged by the company before, during or after the conference. Breaches of the Code have been ruled where companies have disguised company meetings as being connected to scientific congresses. Invitations to the meeting should be open to all *bona fide* attendees of the congress and not controlled by the company.

The requirements of accreditation bodies for Continuing Medical Education should also be considered if this is being sought for the event. These can include a requirement to separate any advertising material from the scientific content in meeting materials such as programmes.

Table 3: Reprints and posters distributed at international congress booths

KEY ISSUE	REFERENCE IN BOOK/CHECKLIST
Is the reprint or poster within the terms of the product licence in the applicable country?	*Check with company national regulatory department or Summary of Product Characteristics for the country where the conference is being held.*
If not, is it within the licence in any country and what are the rules about promotion of unlicensed/ off-label information in the country where the congress is being held?	*Check the legal and Code requirements with the local operating company/affiliate in the country where the congress is being held.*
Check that the reprint/poster gives a balanced/accurate view of the available information?	
Could the reprint or poster be considered to be misleading?	*Refer to Basic Principles: Exaggerated, false or misleading claims.*
Do the applicable codes require reprints to be certified as for other promotional items?	*This is a requirement in the UK.*
Has the paper been published in a peer-reviewed journal/independently refereed?	*If not peer-reviewed it may need to be approved as any other item of promotion and therefore may require integral prescribing information.*
Do the applicable codes require prescribing information to be supplied with the reprint and does this need to be an integral part of the paper or poster or can it/must it be given separately?	*The ABPI Code does not require the PI to be an integral part of the reprint, provided the paper is peer reviewed. Similarly, in most European countries it is sufficient to provide, or have available, a copy of the PI to distribute with the reprint (an SPC alone is not adequate in some countries as this does not include the price). Confirm this locally.*

Table 4: Planning promotional materials for booths at international congresses

ACTION/CHECKLIST	REFERENCE IN BOOK
Is the product or indication licensed in the country where the conference is being held?	*Check with the company's national regulatory department or Summary of Product Characteristics for the country where the conference is being held.*
If not, is it within the licence in any country and what are the rules about promotion of unlicensed/ off-label information in the country where the congress is being held?	*Check the legal and Code requirements with the local operating company/affiliate in the country where the congress is being held.*
Do the materials have to be pre-approved or submitted to the Ministry of Health in any of the countries where they are to be used?	*Check this with the local operating company/affiliate in the country where the congress is being held.*
Does the information have to be in the language where the product is licensed?	*Check with local operating company/affiliate in the country where the congress is being held.*
If licensed, are any claims consistent with the licence?	*Check with company national regulatory department or Summary of Product Characteristics for the country where the conference is being held.*
Are the claims accurate, balanced, based on up-to-date information, capable of substantiation?	*UK requirements: Basic Principles: Substantiation.*
Check what types of references are allowed as standard of proof for substantiation of claim, e.g. is data on file allowed? Some countries only allow peer reviewed published data to be used to substantiate claims.	*Check the requiremets with the local operating company/affiliate in the country where the congress is being held.*
If planning to use the word 'new' check when the word can be used.	*Check the requiremets with the local operating company/affiliate in the country where the congress is being held.*
Check what the relevant code(s) say regarding hanging comparatives, superlatives and quotes.	*For UK requirements, refer to the relevant sections in Basic Principles.*
Check that artwork such as graphs and statistics are not misleading.	*Refer to Basic Principles: Graphs.*
Does the Code specify that a unique identification number is required to be printed on the promotional piece?	*The ABPI Code in the UK requires that when items are certified they are given a unique number and this number should appear on promotional items (see Basic Principles: Unique reference).*
Is a warning symbol required, e.g. black triangle for adverse events?	*Check with local operating company/affiliate (see Basic Principles: Black triangle for UK requirements).*
Is information on how to report adverse events required?	*Check with local operating company/affiliate (refer to Basic Principles: Adverse Events mandatory warning) for UK requirements.*
Is there a requirement for prescribing information to be an integral part of the promotional item/booth panel? And if so, what must this contain?	*The ABPI Code requires PI to be either on the panels or available at the booth (if the latter, a statement is required on the panel to this effect). It is usually required for other materials. Refer to Chapter 3: Printed Materials and Chapter 7: Digital Media for exact requirements. Check with local operating company/affiliate for requirements where congress is being held.*

Although information about a product can be provided under certain circumstances, e.g. legitimate scientific exchange at some congresses, a product must never be promoted prior to its marketing authorization and care must be taken that promotion is not disguised as 'scientific exchange'.

Symposium abstract books

There should not be any reference in writing to the name (either brand or generic name) of an unlicensed product or mention of the use of a licensed product for an unlicensed indication. These materials must not be branded or contain logos.

Invitations to symposia

Invitations to symposia at international congresses may be ruled as promotional and if a product and claim are mentioned in this case they must meet the requirements of a promotional item and will need prescribing information. Additionally they are often distributed by being included in the conference bag which all delegates receive and because some delegates are not HCPs, this may mean that a prescription-only medicine (POM) is being promoted to the general public. It is usual, therefore, for these reasons, for companies to ensure that symposia invitations are non-promotional and just give details of the topic, venue and date of the symposium.

National congresses and meetings in the UK

Promotion at national congresses and meetings in the UK must be consistent with the terms of the licence of the product or products, otherwise the arrangements for international congresses can be followed. The following key issue checklists refer to promotional items, including the booth panels that are to be used in national congresses held in the UK. **N.B.** Companies cannot provide gifts such as conference bags and pass holders. (Refer also to the requirements of printed materials found in **Chapter 3: Printed Materials.**)

Table 5: Reprints and posters distributed from booths at national congresses and meetings

KEY ISSUE	REFERENCE IN BOOK/CHECKLIST
Is the reprint or poster within the terms of the product licence?	*Check with company national regulatory department or Summary of Product Characteristics.*
Confirm that the reprint/poster give a balanced/accurate view of the available information.	
Confirm that the reprint or poster is not misleading.	*Refer to Basic Principles: Exaggerated, false or misleading claims.*
Has the paper been published in a peer-reviewed journal/independently refereed?	*If not peer-reviewed it may need to be approved as any other item of promotion and therefore may require prescribing information.*
Confirm whether the prescribing information is to be supplied with the reprint. Does this need to be an integral part of the paper or poster or can it/must it be given separately?	*This is not required in the ABPI Code provided the paper is peer reviewed.*