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INTRODUCTION TO THE FIFTH EDITION

My aim in first writing 'The Code in Practice' over ten years ago, was to produce a simple, user-friendly, and above all, practical, guide to the ABPI Code of Practice for the Pharmaceutical Industry. I am very pleased that the positive response suggests that this aim continues to be achieved.

In the last edition of this book, I said that my perception was that over the last few years there had been a distinct change of emphasis within the industry, so that it was now less about avoiding doing wrong, and much more about fully embracing the Code and always striving to do right. The emphasis is shifting yet again, with the emphasis now on not only doing right but being seen to be doing right.

This edition has been updated in line with the revised Code which will come into effect in January 2011. The changes are mainly focussed on demonstrating that the industry can be a trusted partner, working with health professionals and the NHS for the benefit of patients. So, out have gone the 'giveaways' - not because of concern that prescribers would be influenced by them, but because being seen simply as a source of free stationery is a barrier to this professional relationship - and in has come Joint Working with the NHS.

Also very much 'in', as a key element of building trust, is greater transparency. The new Code signals future requirements in relation to declaration of payments to patient organisations, consultant fees and support for attendance at meetings.

I very much hope that 'The Code in Practice' will continue to prove a trusted partner in assisting companies to comply with the Code.

Joan Barnard
December, 2010

Is the promotion in good taste?

The Code requires that promotion must:

- recognise the special nature of medicines
- recognise the professional standing of the audience
- be of a high standard at all times
- not be likely to cause offence.

Specific requirements are:

- do not use the naked body to attract attention to material
- do not use sexual imagery to attract attention to material
- do not use extremes of format, size or cost of promotional material

Also be careful with promotion which could be considered unprofessional e.g.

- Gimmicks
- Over-simplistic 'Mickey Mouse' type advertising
- Flashy appearance
- Sexual innuendo.

Although some of the above have been used successfully, considerable judgement is needed and each promotional piece must be assessed on its own merits.

Is the promotion likely to cause offence?

Individuals vary so much that a piece which is quite innocuous to one may be deeply offensive to another. This means it is virtually impossible to guarantee that a piece will not cause offence to someone, however the Code requires only that promotion 'must not be likely to cause offence'.

To reduce the likelihood of material causing offence, it is important to remember that the audience for your promotion will be:

- Professional
- Men and women
- From a wide age range
- Multi-ethnic
- Of a wide range of religious persuasion.

Be particularly careful with humour which can be received very differently by different people.

If a new campaign or advertisement or form of promotion includes anything very 'different' (e.g. a 'novel, exciting idea' from the ad agency) or doubtful, it is a good idea to review it vis a vis the Code at the concept stage - rather than spend a lot of time and money developing a campaign which is then rejected. It would also be wise to test it on a mixed sample of health professionals before proceeding.

TEASER ADVERTISING

Teaser advertising is not acceptable.

Is this a teaser advertisement?

An advertisement is a 'teaser' if it raises interest in something without giving any information about what the 'something' is e.g.

'Coming soon'

'Get ready!'

If the advert does include information about the 'something' e.g.

'Coming soon - a major advance in oncology'

'Get ready for a new approach to pain relief'

it is not a teaser advertisement (although it may be in breach of the Code for other reasons).

ADVISORY BOARD

Is this an advisory board?

An advisory board is exactly that - a board of advisers, who can provide a company with relevant advice.

An advisory board is run for the benefit of the company, and the members of the advisory board provide their advice as a professional service, under contract.

An advisory board differs from other types of meeting, which are educational and are therefore run for the benefit of the attendees.

Is the advisory board set up appropriately?

An advisory board should have a clear objective in relation to the advice which is required, and should be set up in a way which allows this objective to be met.

The objective will therefore determine:

- Selection of members
Members should be selected individually on the basis of relevant knowledge and experience. Members must not be selected on a 'first come, first served' basis.
- Number of members
If the disease of interest is managed by several different specialities, or different types of health professional, it may be necessary to have members representing each of these different groups e.g. hospital consultants, nurses, GPs
- Number of meetings
If the disease of interest is managed very differently in different areas of the country, regional advisory boards may be required

The set up of the advisory board must always be capable of standing up to independent scrutiny.

Does the invitation make it clear that it is an advisory board?

An invitation to an advisory board must provide the recipient with clear information about:

- The purpose of the meeting
- The nature of the meeting
- Why you have selected him
- What you expect him to do at the meeting
- Whether any preparation is required

If possible, an agenda should be included.

A breach of the Code may be ruled if the invitation does not make the nature of the meeting sufficiently clear - even if the actual arrangements for the meeting are acceptable.

Does the invitation comply with the Code?

The initial invitation must comply fully with the Code. If it includes a product name or information about a product, it is promotional, and therefore requires all essential information, including P.I. P.I. should also be included if only the brand name is mentioned.

If the advisory board concerns an unlicensed product or indication, careful wording may be necessary to ensure that the letter provides clear information about the purpose of the advisory board, without mentioning the product and thus promoting prior to licence.

Is the advisory board meeting set up appropriately?

As the purpose of the meeting is to obtain advice and input from the members, the meeting must be set up in a way which allows it to be interactive.

The number of members attending an advisory board should be limited to a number which allows each member to make a meaningful contribution.

Is the content of the advisory board meeting covered by the Code?

In a bona fide advisory board, members are contracted to provide services to the company. The relationship therefore is between a company and a professional adviser. Within this relationship, the content of materials and discussion is not covered by the Code in the same way as promotional material is and it is possible, for example, to discuss unlicensed medicines and indications.

However, if it is deemed that the purpose is not to obtain advice but to promote, then the content would be covered by the Code.

Features which may result in the purpose being considered promotional include:

- Prominent use of the brand name in materials - unless this is essential for the purpose of the Advisory Board
- Prominent branding of materials- unless this is essential for the purpose of the Advisory Board
- Emphasis on presentation rather than on discussion - presentation should be limited to what is necessary to provide a basis for discussion.

If the content is considered promotional, it is likely that the meeting itself will be considered as a promotional meeting and not as an advisory board. Payment to attendees will therefore be unacceptable and in breach of the Code.

Are the arrangements for the advisory board covered by the Code?

All arrangements - venue, accommodation, hospitality - are covered by the Code. The requirements for these are the same as the requirements for any other meeting. The only difference is that air travel for advisory board members is not restricted to economy class.

Is it acceptable to pay a fee?

Members of advisory boards are engaged by a company to provide their professional services i.e. they are engaged as Consultants.

As Consultants, they may be paid an appropriate fee, but this, and all other aspects of the arrangements, must be covered by a Consultant Agreement – see p.204

From 2012, companies will be required to make public information about total fees paid to consultants and associated travel and accommodation costs. There will be no requirement to provide information on individual fees, or for individual consultants to be named. See p.205