

AN INTRODUCTION TO THE ABPI CODE OF PRACTICE, 2011



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1. What is the Code?

The promotion of medicines in the UK is subject to UK and European legislation. All the legal requirements are incorporated in the ABPI Code of Practice (the Code), the self-regulatory system which regulates the promotion of prescription only medicines in the UK.

The aim of the ABPI Code of Practice for the Pharmaceutical Industry is to ensure that the promotion of medicines is responsible, ethical and professional.

All pharmaceutical companies who are members of the ABPI must abide by the Code, and non-members may agree to abide by it. The few companies which do not agree to be bound by the Code are still subject to the legal requirements and their promotional activities are regulated directly by the MHRA.

The Code has been in use since 1958 and is regularly revised, usually every two years, in consultation with the BMA, the RPSGB and the MHRA.

The Code was reviewed during 2010, with a new Code coming into effect on 1 January 2011.

The introduction to the Code sets out the main principles:

- Promoting Appropriate Use of Medicines – there are requirements in relation to both the quality and quantity of promotional material, with major emphasis on patient safety.
- Ensuring High Standards – the Code sets out what is and what is not acceptable in relation to all areas of promotional and non-promotional activity.
- Transparency – it is important that any involvement of a pharmaceutical company in any activity is made clear.
- Sanctions – the Constitution of the Code details the procedures and sanctions which ensure that breaches of the Code are appropriately dealt with.

2. What does the Code cover?

Essentially, the Code covers all promotion of medicines in the UK. Promotion is defined as

"any activity undertaken by a pharmaceutical company or with its authority which promotes the prescription, supply, sale or administration of its medicines"

which means that this term encompasses a wide range of materials produced, and activities undertaken, all of which are subject to the requirements of the Code. And just in case that does not cover everything, 'The Code also applies to a number of areas which are non-promotional.'

The Code therefore applies to everything from advertisements to meetings to sales representatives, and needs to be considered in relation to the activities of not just Sales and Marketing but also, for example, Public Relations, Medical Information and Market Research. It applies to activity a company undertakes itself, and also to activity undertaken on its behalf, for example by advertising or PR agencies.

Although certain specific items are not usually within the scope of the Code, there are circumstances in which they may be considered to be covered, because whether or not something is considered promotion may depend not just on the material or activity itself but also on its perceived purpose, how it is used and its consequences. For example, SPCs are not included in the definition of promotion but if the SPC includes product logos or appears overly promotional in style, it may be considered promotional and thus come within the scope of the Code.

The Code covers the promotion of prescription only medicines. OTC medicines are covered by the Codes of the Proprietary Association of Great Britain.

Medicines can only be promoted to health professionals e.g. doctors, pharmacists, nurses, or appropriate administrative staff e.g. Health Authority executives, Practice Managers. Promotion to the general public is prohibited.

The Code covers:

- Materials or activities directed towards a UK audience
- Materials used or activities which take place in the UK, whether or not there are UK recipients or participants.
- Materials produced or activities undertaken by a UK company (this includes not only UK marketing companies but also the Global or International divisions of UK-based companies).

3. Promotional Material

Promotional material can range from one page advertisements to large product monographs, and may appear in various forms – print, audiovisual, digital, Internet. Regardless of form and format, the following Code requirements always apply.

A product (or an indication) can only be promoted if it has a UK **marketing authorisation**. There are certain specific circumstances in which companies can provide information about an unlicensed medicine or indication – but this must always be information, never promotion.

All statements and claims about a product must be **consistent with the SPC**, particularly in terms of dosage, patient population, use with other medications, contra-indications and adverse events. This means for example, that if a product is licensed for use only in adults, it cannot be promoted for use in children.

Promotion should encourage informed prescribing decisions. All statements, including comparisons with other products, must be **accurate, balanced, up to date and not misleading**. This is one of the most difficult areas in the Code and

the one which probably gives rise to more complaints than any other. Whether or not a piece is misleading is ultimately a subjective judgement, but can depend on whether or not the content is clear, precise and unambiguous; whether any information which might alter the meaning of the statement has been omitted; whether the context - the headline, the positioning or prominence of the statement - creates a misleading impression. It can also depend on the intended reader and the intended use of the piece. The benefit/risk profile of a medicine should always be made clear.

Specific examples of misleading statements include **hanging comparisons** a comparison which can be followed by the question "compared to what?" e.g. 'Persil washes whiter'; **superlatives**, unless they can be substantiated; **exaggerated claims** for a 'special quality' of a product e.g. 'unique', 'brilliant'. The word **safe** (and related words such as 'safety') must not be used without qualification. Data derived from **non-clinical studies** e.g. in vitro or human volunteer studies, can be used only if it is made clear that the studies are not clinical and only if the clinical relevance of the data can be demonstrated.

Care needs to be taken with **graphs, figures and artwork**, to ensure that these are not misleading. Artwork also needs to be professional and 'not likely to cause offence'. This is not always easy to predict.

All statements must be **capable of substantiation** i.e. supported by data which is relevant and available (not copyright or privileged). This is usually done by providing references to support each statement. Appropriate substantiating data must be provided to anyone who requests it – including employees of other companies.

Prescribing Information (P.I.) is a succinct summary of the information in the SPC which a doctor needs before making a decision to prescribe a medicine for a patient. It includes the indications, contra-indications, side effects and cost. P.I. is required on every piece of promotional material (with a few, very specific, exceptions). There are specific requirements for how the P.I. should appear in various different types of item, but it must always be presented clearly and legibly.

All of the requirements above apply to promotional material in any form, including on the **Internet**. For promotional material included on a website, access should generally be restricted to health care professionals, for example by password protection. If access is not restricted, information must also be provided for the general public, so that it is not necessary for them to access the health professional site. The intended audience should be clearly identified on all areas of a website.

4. 'Gifts'

A company must not give a doctor anything which is, or could seem to be, an inducement to prescribe, supply, administer, recommend or buy any product i.e. the offer of the gift must be **unconditional**.

Companies cannot offer any items as part of promotional activity. Doctors and other attendees can be provided with pens, pencils and pads to take notes at meetings, but the items must be inexpensive, defined as no more than £6.00, excluding VAT in total. These items can be provided only at meetings, not by representatives during call, and not from exhibition stands.

Items intended to benefit patients e.g. pedometers to encourage exercise, can be provided to doctors so that they can then be distributed to appropriate patients. Again, these items must be inexpensive, they can be provided to doctors by representatives during calls, but cannot be given out from exhibition stands.

Meeting materials and items for patients are referred to in the Code as 'promotional aids', but they must not be product branded or include any information about a product; they can be corporate branded.

Competitions, quizzes and prizes are not considered acceptable methods of promotion.

More expensive items or services can be provided but special conditions apply. The Code terms these **Medical and Educational Goods & Services (MEGS)**; examples would be providing nurses to undertake an audit of treatment in a particular disease area or a piece of diagnostic equipment or an educational programme. They must enhance patient care or benefit the NHS and they must be **non-promotional**. This means that they should not be associated with any product and should not be used promotionally. It also means that representatives should not be involved too closely, if at all. There must be **no conditions** attached to the goods or services e.g. they must not be provided only to those who prescribe a particular product. Anyone involved in providing the service must be appropriately qualified and patient confidentiality must be maintained at all times. Detailed documentation is required to cover all aspects of the arrangements.

Companies can work in partnership with the NHS for the benefit of patients on a wide range of projects – this is termed '**Joint Working**'. In Joint Working, all parties make a significant contribution to the project – this is one difference between joint working and MEGS, where the company is likely to provide most of the resources. Joint working arrangements must be carefully documented and must be made public.

Samples of medicines can be provided to allow doctors to familiarise themselves with the use of a medicine. There are restrictions on which medicines can be offered, the size and number of samples which can be provided, how they are delivered and who can receive them. Full records must be kept of all samples issued.

5. Meetings

Companies organise a huge variety of meetings, ranging from small lunchtime meetings in GP surgeries to large national symposia. The overriding requirement for any meeting is that it must have a clear educational content, and that this must be – and must appear to be – the main purpose and attraction of the meeting. With any meeting, the impression given is of utmost importance.

It follows therefore that any hospitality must be secondary i.e. subsistence only. It must be appropriate to the attendees, with costs being no more than attendees would be expected to pay for themselves. It must also be appropriate to the occasion, for example, overnight accommodation can be offered only if this is justified by the programme. Lavish, extravagant or deluxe venues must not be used and nor should venues renowned for their entertainment facilities. Sporting activities cannot be included nor can any other activity, such as wine tasting, which is not considered 'professional'. Hospitality can be offered only to attendees of the meeting, not to persons accompanying them.

A company is responsible for ensuring that all materials associated with a meeting e.g. invitation, programme, and all content, including presentations by internal and external speakers, comply with the same Code requirements as apply to promotional material. The Code also requires companies to have a written agreement in place with speakers and chairs of meetings.

All of this applies to all meetings attended by UK health professionals, administrative staff, members of the public, patient groups or journalists, whether the meetings are educational or promotional and whether the meetings are held in the UK or elsewhere. Meetings can be held outside the UK only if most of the invitees are from outside the UK or if it is logistically necessary given the subject of the meeting. The location cannot be the main attraction of the meeting.

These requirements also apply to any meeting which takes place in the UK, whether or not there are any UK attendees, and to any meeting organised by a UK company, wherever the meeting is held.

6. General Public

Prescription only medicines must not be promoted to the general public.

Information can be provided to the public. It must be factual, balanced and not misleading and must not raise unfounded hopes of successful treatment. Most importantly – and this really represents the difference between 'promotion' and 'information' – it must not encourage any individual to ask his doctor to prescribe a specific medicine.

The Code recognises a number of categories of information for the public:

Reactive information is provided in response to a direct request, usually via Medical Information. The information must be limited to what is necessary to respond to the request and it must not relate to personal medical matters or intervene in any way in the patient/doctor relationship.

Proactive information is supplied without a request e.g. booklets on diseases or medicines. This also includes press activity and disease awareness campaigns.

Disease awareness campaigns are acceptable provided they do exactly that, namely make the public aware of a disease, or symptom(s), or health issue. They can encourage individuals to consult their doctors to seek treatment but they must not, either directly or indirectly, suggest any specific treatment. This means that a Disease Awareness Campaign is very different from 'DTC' – direct to consumer advertising, which is prohibited both by the Code and by the Advertising Regulations.

Reference information is defined as a comprehensive up-to-date, library resource on POMs for the public which can be provided on a company website. It must include the SPC, PIL and any Public Assessment Reports, but can also include detailed information about diseases, specific medicines, clinical studies etc.

Companies can work with **patient organisations**, and can provide a substantial amount of information to them. All arrangements with patient groups must be covered by a written agreement and details of all financial support must be published.

7. Public Relations

In many ways, as far as the Code is concerned, PR material is no different from promotional material in that the content must be accurate, not misleading etc. PR material needs to be reviewed just as thoroughly as any other material. However, there are two significant differences.

Part of PR activity is to publicise important news about a company and its products. There may be occasions when the 'important news' concerns unlicensed medicines or indications, and this information may be directed not only to the medical press but also to the public. This is recognised as a legitimate business activity for a pharmaceutical company to undertake and is acceptable under the Code, provided that the 'important news' really is both news and important e.g. the publication of the results of a clinically important study. The information must always be presented factually, and must not be promotional, either in content or style. The business importance of the information should be made clear.

It is important to distinguish between material for the medical and trade press e.g. BMJ, Lancet, GP, Nursing Times, Scrip, and material intended for the consumer press e.g. newspapers and magazines – what may be considered 'important news' for doctors, may not be for the general public.

Financial information made available to the Stock Exchange, financial analysts, financial press etc, may relate to both licensed and unlicensed medicines, provided the information is factual and balanced.

8. Representatives

Given that their role is to sell, representatives must be considered as primarily promotional, so the Code covers all aspects of their work. Representatives are required to maintain a high standard of ethical behaviour at all times.

Everything that representatives say during calls, or at meetings, is subject to the same requirements as printed material i.e. it must be accurate, not misleading etc.

They must always treat doctors' time with respect, make sure that calls are convenient and limit calls to no more than three on average per doctor per year. They must not use any inducement or pay any fee for an interview. Insisting on delivering a requested item to a doctor, rather than leaving it with the receptionist, or offering a donation to charity in return for an interview, would be considered inducements.

Any letters written by representatives are almost certain to be considered promotional and are therefore subject to all requirements of the Code. For this reason, many companies insist that representatives use only standard letters.

Representatives must be given appropriate training on the products to be promoted and on the Code of Practice. All training materials are subject to the Code and must be certified. Briefing materials - any instructions given to representatives on how a product should be promoted e.g. sales conference presentations, memos – are also subject to the Code and must be certified.

Representatives must pass the ABPI Representatives' Examination within the first 2 years of their employment as a representative.

9. Other Areas

There are other, essentially non-promotional areas, which are not usually covered by the Code, but can fall foul of the Code if they are not conducted in a way which makes them promotional.

Market Research should be carried out in an unbiased and non-promotional way. If it is done in a way which promotes a product, this would be a breach of the Code.

In **Clinical Research**, any clinical study should have a valid medical objective and should be designed so that it can achieve that objective. A study which is set up mainly to encourage the use of a product, or which recruits more patients than can be statistically justified is likely to be considered disguised promotion, in breach of the Code.

Medical Information letters are exempt from the Code, so can include reference to unlicensed products or indications – but only if the letters are sent in response to an individual, unsolicited enquiry and the reply relates solely to the subject of the enquiry and is accurate, not misleading, and not promotional in nature.

10. How does the Code operate?

The Code is administered by the **PMCPA**, which was established by the ABPI to operate the Code at arms' length from the ABPI itself.

A key point about the Code is that it operates as a **complaints system**, not as a policing system. Complaints can be sent to the PMCPA by any individual or organisation, including health professionals, pharmaceutical companies and the media. Complaints can also be submitted anonymously.

Details of any complaint about a company's promotion are sent to the company, which then prepares a written response. The complaint and the response are considered by the **Code of Practice Panel**, which decides which clause(s) of the Code, if any, have been breached.

A Panel ruling can be appealed by either party, and the matter is then considered and ruled on by the **Code of Practice Appeal Board**, which includes both industry and independent members, medical and non-medical members and a member who represents patient interests. It has an independent, legally qualified chairman. Both parties submit written evidence and may also choose to appear in person before the Appeal Board. The decision of the Appeal Board is final.

If an ABPI-member company is found in breach of the Code, it must pay 'administrative charges'. These are set at a level to allow PMCPA to be self-financing. They are not intended to be fines. Any activity ruled in breach must cease immediately and any material ruled in breach must be withdrawn from use. If this involves a core aspect of a campaign, withdrawal can be a complicated and expensive undertaking.

A serious case may result in a ruling of a breach of **Clause 2** of the Code, for 'bringing discredit upon, or reducing confidence in, the pharmaceutical industry'. Particularly serious cases may result in a public reprimand, an audit of the company's procedures, the publishing of a corrective statement or a report to the Board of Management of the ABPI who may suspend or expel the company from the ABPI.

When a case has been completed, a detailed case report is published by the PMCPA on its website and in the **Code of Practice Review**, which appears quarterly. The case report names the company complained about and any company which makes a complaint, but does not name any individual complainants such as doctors or pharmacists. Case reports are thus made widely and freely available to the industry and outside, and serious cases are often featured in the medical and lay press.

11. How does a company stay within the Code?

As can be appreciated from all of the above, there are many areas of activity, and many functions, within a company which are affected by the requirements of the Code. To stay within the Code, a company therefore needs to ensure that all areas of activity are covered by appropriate procedures and that all relevant staff are trained on the Code. All staff also need to understand and follow all procedures relevant to their function.

Before it can be used, all **promotional material** must be 'certified'; this means that two senior members of a company, one of them a doctor, or in some instances, a pharmacist, must sign the material, certifying that it complies with all requirements of the Code. This process is **certification** and the people who sign are **signatories**.

All material must be certified 'in its final form', which usually means that it is a final printed version which is certified. So, for example, a detail aid is printed and then certified before it is sent out to be used by the representatives. It is obviously very costly to print material which cannot be certified because it does not meet Code requirements, so all companies have a system which involves drafts being reviewed and revised until the material is acceptable; it can then be printed or produced.

The details of this **Copy Approval System** will vary from company to company, in terms of the people involved, the procedure and the administration. Reviewers will always include Medical, usually Marketing and Medical Information, and possibly Regulatory Affairs and Legal Departments. The procedure will consist of anything from two or three to more than a dozen steps. Effective administration of the system is extremely important, to allow material to be approved as quickly as possible, and also to ensure that all the required documentation is obtained and filed appropriately. (Material must be re-certified at two year intervals if still in use and certified material and certificates must be kept for at least 3 years after final use.)

In addition to promotional material, all **meetings** which involve travel outside the UK must also be certified in advance as must certain **non-promotional material** – educational material for the public, patients and patient organisations and material related to the provision of medical or educational goods or services and to joint working arrangements. Other items such as Press Releases should be examined to make sure that they do not contravene the Code. Companies either include these in the Copy Approval System or have another, similar system for examination only.

There needs to be a procedure for the **withdrawal of promotional material** so that it cannot be used again. This procedure is particularly important if the material is being withdrawn because it has been ruled in breach, but is also useful when material is being replaced for marketing or administrative reasons. The procedure needs to cover everything from leavepieces being used by representatives to advertisements and needs to ensure that all copies are withdrawn and destroyed. This can be a very complicated administrative task.

A company is expected to ensure that all staff, including third party staff, who are involved in any way with activities covered by the Code receive appropriate **training**. The amount, and content of training will vary with the individual's role. Those who are only peripherally involved with the Code may need no more than this brief introduction, while signatories will need considerable knowledge and experience of the Code. Representatives will need to focus on quite different areas from Public Relations.

A company thus has to devote a huge amount of effort to enable it to keep within the Code.

This introduction should help you to understand how the Code might affect what you do in your function.

Further reading

ABPI Code of Practice for the Pharmaceutical Industry 2011 (see www.pmcpa.org.uk to order or download copies)

The Code in Practice by Dr Joan Barnard. How to follow the ABPI Code of Practice when producing and reviewing promotion.

The Code in the Field by Dr Joan Barnard. A practical guide to the ABPI Code of Practice for Medical Representatives.

GLOSSARY

ADMINISTRATIVE STAFF – healthcare staff who do not qualify as Health Professionals but whose position means that they have a valid interest in or need of information about medicines e.g. Health Authority Managers, Practice Managers.

ADVERSE EVENT – an unexpected or unpredicted reaction to a drug, unrelated to the drug's usual effect.

ABPI – The Association of the British Pharmaceutical Industry, the trade association representing manufacturers of prescription medicines. It represents a large number of companies which produce over 80% of the medicines supplied to the National Health Service.

BMA – British Medical Association.

CERTIFICATION – the final approval of promotional and certain non-promotional material by senior members of a company, who certify that the material complies with the Code.

CODE OF PRACTICE PANEL – the body within the PMCPA which first considers and rules on complaints. The members of the Panel are staff of the PMCPA.

CODE OF PRACTICE APPEAL BOARD – the Appeal Board consider cases where the ruling of the Code of Practice Panel has not been accepted, either by the complainant or the respondent. The Appeal Board consists of industry and non-industry, medical and non-medical members.

CONTRA-INDICATION – diseases, conditions or situations in which, for safety reasons, a drug must never be used.

HEALTH PROFESSIONAL – professionals who may prescribe, supply or administer medicines e.g. doctors, dentists, pharmacists, nurses.

INDICATION – a disease or condition for which a drug is approved for use.

MARKETING AUTHORISATION – must be granted by the MHRA before a company is allowed to market a medicine.

MHRA – Medicines and Healthcare products Regulatory Agency, part of the Department of Health, responsible for authorising the marketing of medicines and for monitoring all aspects of their use.

OTC MEDICINE – a medicine which can be advertised to the public and sold 'over the counter' (hence OTC) without a prescription. OTC medicines can also be prescribed by doctors.

PRESCRIBING INFORMATION (P.I.) – the essential facts about a medicine, based on the SPC. The contents of P.I. are specified by the Code.

PMCPA – Prescription Medicines Code of Practice Authority, the body set up by the ABPI to administer the Code.

PRODUCT LICENCE – see Marketing Authorisation.

RPSGB – Royal Pharmaceutical Society of Great Britain.

SAMPLE – a small supply of a medicine provided so that Health Professionals can familiarise themselves with it.

SPC or SmPC – Summary of Product Characteristics. Detailed information about all aspects of a medicine relevant to its use, including dose, indications, contra-indications, adverse events. The SPC is agreed with the MHRA prior to the granting of the Marketing Authorisation and all marketing of the medicine must be consistent with the SPC.