

A QUICK GUIDE FOR PATIENTS AND THE PUBLIC TO THE ABPI CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY

The ABPI Code of Practice controls how pharmaceutical companies can promote prescription medicines to health professionals in the UK and the information they can provide about prescription only medicines to patients and the public.

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1 Why is there a Code of Practice?

The Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry exists to ensure that the promotion of prescription medicines to health professionals and others is carried out in a responsible, ethical and professional manner in the UK. The Code also covers the provision of information about prescription only medicines to the public. It is designed to help ensure high professional standards within the pharmaceutical industry.

The ABPI is the trade association for more than seventy-five companies in the UK producing prescription medicines. All pharmaceutical companies which are members of the ABPI are required to adhere to the Code and about fifty non-member companies have also agreed to abide by it. The Prescription Medicines Code of Practice Authority (PMCPA) administers the ABPI Code at arm's length from the ABPI itself, investigates any alleged breaches of the Code and takes action when a breach is ruled.

Self regulation is supported by the Medicines and Healthcare products Regulatory Agency (MHRA), which is responsible for administering UK law. Self regulation is seen as the first means of dealing with complaints, but the MHRA will take action if complaints cannot be resolved by the PMCPA or there are public health concerns. The relationship between the PMPCA and the MHRA is set out in a memorandum of understanding which is available from the PMCPA website at www.pmcpa.org.uk.

2 What does the Code cover?

The Code covers all aspects of the promotion of prescription medicines to UK health professionals and appropriate administrative staff including NHS managers. It also covers some areas that are non-promotional, including information made available to the public about prescription only medicines. For the first time, the 2006 edition of the Code sets out specific requirements for relations between pharmaceutical companies and patient organisations.

The Code does not cover the promotion of over-the-counter (OTC) medicines when the object is to encourage purchase by the public. Promotion of OTC medicines is covered by another trade association, the Proprietary Association of Great Britain (PAGB).

3 Why does the Code matter to me?

Most of the Code deals with the promotion of medicines to health professionals (eg doctors, pharmacists and nurses etc). To ensure appropriate relationships between health professionals and patients, prescribing decisions must be based on what is best for patient care and not influenced by the relationship between the prescriber and the pharmaceutical company. The Code also covers relations between pharmaceutical companies and the public. Patients need a range of sources for good quality information about medicines including the companies that have researched and developed them.

Clause 20 of the Code sets out how pharmaceutical companies are permitted to interact with the public and patient groups. If you feel that a pharmaceutical company has breached the Code, you can raise your concerns with the PMCPA. This will help ensure that information provided to the public about prescription only medicines is appropriate.

Health professionals can, and do, make complaints to the PMCPA if they feel that any company, or representative from a company, has breached the Code. The Code bans any promotion of a medicine to health professionals before it has been authorized for sale, sets out what prescribing information and other obligatory information must be given when medicines are promoted and details training requirements for pharmaceutical sales representatives (who promote to doctors and other health professionals). The level of hospitality that pharmaceutical companies can offer to health professionals and others is also strictly controlled as is the distribution of samples. The Code states that the provision of medical and educational goods and services to surgeries (such as the services of nurses who are sometimes provided by pharmaceutical companies to carry out audits etc) must be kept completely separate from the promotion of medicines and any materials that are sponsored by a pharmaceutical company must be clearly marked as such. There are also limits on items used as promotional aids eg pens and pads etc. If health professionals feel that any of these requirements are being breached, they are encouraged to contact the PMCPA.

A separate booklet highlights to health professionals the key parts of the Code for them. This booklet is available from the PMCPA website and is distributed to health professionals through various channels.

4 What role do I have?

Patients and members of the public have a role to play in monitoring information provided to them by making complaints if they feel the Code has been breached. This will help maintain the effectiveness of the system and standards within the industry.

Very few complaints have been submitted by members of the public to-date. In 2006, out of a total of 134 complaints, 57 were from health professionals (mainly doctors, pharmacists and pharmaceutical/medical advisers) and 23 from pharmaceutical companies. The majority of the remainder arose from the Director of the PMCPA. Only three complaints were made by members of the public in 2006 – though this was a slight rise from the previous year when only one complaint was made by a member of the public. Full details are given in the PMCPA Annual Report available from the website www.pmcpa.org.uk.

5 How are complaints dealt with?

Complaints about activities and materials covered by the Code can be submitted by anyone and should be sent to the Director of the PMCPA.

Complaints are ruled upon in the first instance by the Code of Practice Panel, which is made up of the Director, Secretary and Deputy Secretary of the PMCPA, taking independent advice as required. If ruled in breach of the Code, the company concerned may appeal the matter to the Code of Practice Appeal Board. In certain circumstances, the Panel can suspend the use of the material or activity whilst awaiting the final outcome of the case. Similarly, if the Panel rules no breach of the Code, the complainant may appeal, but does not have to appear.

The Appeal Board has an independent, legally qualified Chairman, eight other independent members (mainly health professionals but including a member who

represents the interests of patients and a member who is not a health professional) and twelve senior executives from pharmaceutical companies.

Companies found in breach of the Code must immediately withdraw the relevant material or cease the activity concerned. In addition, the following sanctions can be imposed:

- An audit (to be carried out by the PMCPA) of a company's procedures to comply with the Code, possibly followed by a requirement that promotional material be submitted for pre-vetting for a specified period.
- The recovery of promotional items from those to whom it has been given.
- Publication of a corrective statement.
- A public reprimand.
- Suspension or expulsion from the ABPI.

The PMCPA also advertises brief details of serious cases in the medical and pharmaceutical press.

In every case where a breach is ruled, administrative charges are paid by the company ruled in breach. In cases where another pharmaceutical company is the complainant, and no breach is ruled, the complainant company will pay the charges. However, there is no charge whatsoever for complaints from patients or members of the public.

6 What does the Code say?

The Code covers all aspects of the promotion of prescription medicines to UK health professionals and managers including:

- journal and direct mail advertising;
- activities of pharmaceutical sales representatives;
- supply of samples;
- provision of inducements (either in money or in kind);
- provision of hospitality for promotional purposes;
- sponsorship of promotional meetings;
- sponsorship of scientific meetings (including payment of travelling and accommodation expenses); and
- all other sales promotion (including exhibitions and the Internet).

The promotion of a medicine prior to the grant of its marketing authorization (product licence) is prohibited by UK and EU law. Promotion has to be in line with the marketing authorization and not inconsistent with the summary of product characteristics (Clause 3). Generally when a medicine is promoted prescribing information has to be provided. The prescribing information is a summary of the information in the Summary of Product Characteristics (SPC) which is required by law. In printed promotional material details of how to report adverse events must be given (Clause 4). There are limits on the amount of advertising (Clause 6). Promotional material and claims, including those made verbally, must be capable of substantiation as well as being accurate, balanced, fair, objective and unambiguous. Material must be based on an up-to-date evaluation of all the evidence and not be misleading or exaggerated. Care needs to be taken in relation to side effects (Clause 7). Promotional material must not be disguised and must be tailored to the audience (Clauses 10 and 12).

Sales representatives have to behave ethically and comply with the Code. They must not employ any inducement to gain an interview. No fee must be paid or offered for an

interview. Companies have to prepare briefing material for representatives explaining about the product and how it is to be promoted (Clause 15). All relevant personnel have to be trained and representatives have to pass an examination (Clause 16).

There are detailed requirements for the supply of samples and medicines (Clause 17). Promotional gifts must be relevant to the recipient's profession (usually medicine or pharmacy) and cannot cost or be seen as costing more than £6 plus VAT. Gifts, benefits in kind or pecuniary advantage cannot be offered or given as inducements to prescribe, supply, administer, recommend, buy or sell any medicine. Companies can provide medical and educational goods and services to enhance patient care or to benefit the NHS and maintain patient care. Such goods and services are highly controlled and cannot be linked to the promotion of a medicine (Clause 18). The requirements for meetings of health professionals etc are similar to those for patients etc outlined below (Clause 19 and 20).

More detail on these aspects can be found in the Code itself or in the 'Guidance Notes for Health Professionals – Understanding the ABPI Code of Practice for the Pharmaceutical Industry'. Both publications can be downloaded from the PMCPA website at www.pmcpa.org.uk.

The sections of the Code that deal with relations with the public and patient groups are explored below.

a) Advertising medicines to the public

Prescription only medicines must not be advertised to the public (Clause 20.1). The only exceptions to this are vaccination campaigns which are approved by the health ministers.

The advertising of prescription only medicines to the public is also prohibited by UK and European law.

b) Information on prescription only medicines for the public and patients

All information about prescription only medicines that is made available to the public either directly or indirectly must be factual and presented in a balanced way. It is important that information does not raise unfounded hopes for successful treatment or mislead with respect to the safety of the product. The information provided must not encourage members of the public to ask health professionals to prescribe a specific prescription only medicine (Clause 20.2).

Three types of information about prescription only medicines can be made available to the public-

- **Reactive information** – information given to individuals in response to enquiries. This information must be of a factual, non-promotional nature and must not be advice on personal medical matters. It must be limited to what is necessary to respond to the request.
- **Proactive information** – information supplied to the public without a direct request. This includes booklets on diseases and/or medicines supplied directly or via a health professional, press releases, briefings, conferences, mailings to patient organisations and disease awareness advertising. All information must be factual and non-promotional.

- **Reference information** – a comprehensive, up-to-date resource that companies should make available to the public on their website or by some other means. Reference information must represent the current body of evidence relating to a medicine and its benefit/risk profile. Companies are not obliged to provide reference information, but it is considered good practice to provide, as a minimum, the regulatory information. This comprises the summary of product characteristics (SPC), the package information leaflet (PIL) and the public assessment report (PAR) (UK or European).

Information made available to the public must be factual, balanced and non-promotional and adhere to the requirements of Clause 20.2 and its supplementary information.

The introduction of a new medicine must not be made known to the public until reasonable steps have been taken to inform medical and pharmaceutical professionals of its availability (Clause 20.5).

c) What can be said?

What can be said when talking to the public about prescription only medicines is controlled by the Code? All information, claims and comparisons about prescription only medicines must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence (Clause 7.2).

For example, the word 'new' must not be used to describe any product that has been generally available for more than 12 months (Clause 7.11). The word 'safe' must not be used without qualification and expressions such as 'demonstrated safety' or 'proven safety' are not permitted (Clause 7.9). A superlative (such as best or strongest etc.) should only be used if it can be substantiated as a simple statement of fact which can be clearly demonstrated (Clause 7.10). Great care also must be taken with use of the word 'the' (as it can imply a special merit) and 'unique' where it is used to imply a general superiority (Clause 7.10).

d) Information/advice on personal medical matters

Pharmaceutical companies cannot give advice on personal medical matters to members of the public. Individuals should be encouraged to contact their own doctor or other prescriber or health professional (Clause 20.4). This is to ensure that pharmaceutical companies do not intervene in the patient/prescriber relationship by offering advice or information that should be provided by the doctor or other prescriber.

Pharmaceutical companies can provide information to support the use of medicines, such as emergency advice in the event of an overdose or advice on storage. Companies can refer enquirers to other sources where appropriate, such as NHS Direct and patient organisations.

e) Meetings and hospitality

Meetings organised by pharmaceutical companies for, or attended by, members of the public, journalists and patient organisations must comply with Clause 19 of the Code.

When meetings are sponsored by pharmaceutical companies, this must be disclosed on all papers relating to the meeting and the declaration must be sufficiently prominent to ensure that those attending are aware of the sponsorship from the outset (Clause 19.3).

The main purpose of any meeting must be educational and this is what should attract delegates. Meetings must only be held in appropriate venues, suitable for the main purpose of the meeting – lavish and deluxe venues must not be used and companies should avoid using venues that are renowned for their entertainment facilities. Hospitality must be secondary to the main purpose of the meeting and must be modest and not exceed the level which those attending would normally pay for themselves (Clause 19.1).

f) Relationships with patient organisations

Pharmaceutical companies are permitted under the Code to interact with patient organisations and other organisations such as disability organisations, carer and relative organisations and consumer organisations to support their work, as long as all involvement is declared and transparent (Clause 20.3).

Companies are required to list, either on their websites or in their annual report, all patient organisations that they support financially. They must also have in place a written agreement with each organisation setting out exactly what has been agreed in relation to every significant activity or ongoing relationship.

Educational materials for the public or patients and materials relating to working with patient organisations issued by companies which relate to diseases or medicines must be certified by the pharmaceutical company concerned before they are distributed. Certification means that the materials have been examined in their final form by two people on behalf of the company (at least one of whom must be a health professional) who sign to certify that the material complies with the Code. In addition, non-promotional materials for patients or health professionals relating to the provision of medical and educational goods and services, including relevant internal company instructions, must also be certified (Clause 14.3).

Patient groups highlighted some concerns that they were experiencing in relation to the new requirements for written agreements and certification to the PMCPA and the ABPI.

Written agreements were commonly used before the Code required them but their inclusion led to some companies drawing up complex documents which on occasion made agreeing projects with industry time consuming and costly. In order to help, a template for written agreements was drawn up and is available on the ABPI and PMCPA websites.

Concern was also expressed that the additional requirements for formal certification, would cause delays due to time pressure on those that certify material for companies. The PMCPA has issued guidance on certification to help ensure that the system is managed as smoothly as possible so that the industry and patient groups meet jointly agreed deadlines.

g) ABPI Guiding Principles for working with patient groups

In addition to the Code, 'ABPI Guiding Principles for the pharmaceutical industry and patient groups working together', which compliment some of the requirements of the Code in relation to patient groups, are available from the ABPI and PMCPA websites.

h) The Internet

Promotional material about prescription only medicines on a UK company website or a UK company sponsored website is normally required to be access restricted to exclude the public. If this is not done, the website should provide information for the public as well as health professionals, with each section separate and clearly identified (Clause 21.1).

The MHRA Blue Guide (The Blue Guide – Advertising and Promotion of Medicines in the UK, 2005) also states that the public should not be encouraged to access material which is not intended for them and that each page of an advertisement for a prescription only medicine should be clearly labelled as intended for health professionals (supplementary information to Clause 21.4).

7 Conclusion

This booklet is designed to highlight parts of the ABPI Code relevant to you as a patient, a member of the public or a member of a patient organisation.

If you feel that a pharmaceutical company has breached the Code, please get in touch with the PMCPA. Your help is important to ensure that information made available to the public about prescription medicines is accurate and balanced and that the promotion of prescription medicines in the UK is carried out, where permissible, in an appropriate and ethical manner.

To find out more

Copies of the ABPI Code of Practice for the Pharmaceutical Industry (2006) can be downloaded from the PMCPA website at www.pmcpa.org.uk. Hard copies can be ordered by calling 020 7747 8880.

Reports on cases that have been considered under the Code are published in the quarterly *Code of Practice Review*. The review is available to download from the PMCPA website at www.pmcpa.org.uk and is available on request. The website also gives brief detail of ongoing cases and reports of completed cases not yet published.

Other organisations

Medicines and Healthcare products Regulatory Agency (MHRA)
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