PRESCRIPTION MEDICINES
CODE OF PRACTICE AUTHORITY

Guidance notes for health professionals

Understanding the ABPI Code of Practice for the Pharmaceutical Industry

Controls on the promotion of prescription medicines in the UK

2006

THE ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY

The Association of the British Pharmaceutical Industry is the trade association that represents prescription medicine companies involved in every stage of research, development and manufacture of both branded and generic products in the UK. ABPI members supply more than 80 per cent of the medicines prescribed through the National Health Service.

The Association represents the views of the pharmaceutical industry to Government, politicians, the media, the scientific and medical world and the public and provides a wide range of services and support for its members. In addition to the main office in London it also has offices in Scotland and Wales.

THE PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY

The Prescription Medicines Code of Practice Authority was established by The Association of the British Pharmaceutical Industry in 1993 to operate the Code of Practice for the Pharmaceutical Industry independently of the Association itself.

Complaints about the promotion of medicines should be submitted to the Director of the Prescription Medicines Code of Practice Authority, 12 Whitehall, London SW1A 2DY, telephone 020-7930 9677, facsimile 020-7930 4554, email complaints@pmcpa.org.uk.

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Dear Colleague February 2006

Controls on the promotion of prescription medicines in the UK

The Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry, backed by statutory control, is the means by which the promotion of prescription medicines is regulated in the UK. Better understanding of the Code among health professionals and managers will, I believe, increase confidence in the pharmaceutical industry's materials and activities.

The Code and its operation were recently reviewed following wide consultation with stakeholders. The review resulted in many changes, including a requirement for all printed promotional material to provide information about reporting adverse events, restrictions on sponsored travel and more restrictions on hospitality and promotional aids. Relationships with patient groups and the provision of information to the public are covered in greater depth. Further limitations on the amount of advertising have been added. Additional sanctions have been introduced and changes have been made to speed up the complaints procedure.

The main provisions of the Code, listed below, are described in more detail in this document:

- **Scope** The Code covers the promotion of medicines for prescribing to health professionals and NHS managers and information about prescription only medicines intended for the public. It is drawn up in consultation with the British Medical Association, the Royal Pharmaceutical Society of Great Britain, the Medicines and Healthcare products Regulatory Agency (MHRA) and the Royal College of Nursing.
- **Accuracy** Two senior officials of the originating pharmaceutical company, one of whom must be a registered medical practitioner or, in certain circumstances, a UK registered pharmacist, must certify in advance promotional material and certain other material and activities. Information, claims and comparisons must be accurate, balanced, fair, objective, unambiguous and must not mislead.
- **Sales force** Representatives must be trained in the Code and have sufficient scientific knowledge to enable them to provide appropriate information about the medicines that they promote. They must pass the ABPI medical representatives examination. The Code applies to what they say as well as the material they use.
- **Goods, services and promotional aids** Medical and educational goods and services that will enhance patient care or benefit the NHS and maintain patient care can be provided to health professionals and managers if this does not constitute an inducement to use a medicine. Promotional aids can be given if they are of low value and relevant to the recipient's profession.
- **Hospitality and sponsorship** Hospitality can only be provided to health professionals and managers as part of scientific or promotional meetings. Hospitality must be secondary to the meeting, and of an appropriate standard. Lavish or deluxe venues must not be used. Only economy air travel can be provided for delegates sponsored to attend meetings.

- **Samples** Samples of medicines can only be supplied in response to written requests and no more than ten samples of a medicine may be provided in the course of a year to a health professional qualified to prescribe that medicine.
- **Promotion before regulatory approval** A medicine must not be promoted prior to being authorized for UK use. An exception is factual information made available as advance notification to those responsible for policy decisions, so that the NHS can plan financially for a new medicine or indication which has significant budgetary impact. In addition, international meetings held in the UK may include promotion of medicines not approved in the UK but approved elsewhere so long as detailed criteria are met, including the attendance of a significant proportion of non-UK delegates.
- **Prescribing information** Prescribing information must be provided in all promotional material, with the exception of abbreviated advertisements and those promotional aids that incorporate no more than the brand name or non-proprietary name of the medicine and the name of the company.
- **Disguised promotion** Promotional material must not be disguised. Sponsorship by a pharmaceutical company must be declared.
- **Promotion to the public** Prescription only medicines must not be advertised to the public, with the exception of vaccination campaigns approved by health ministers. Non-promotional information can be provided to the general public directly or via the media.
- **Complaints** Instances where materials or activities are considered not to comply with the Code should be referred to the Director of the Prescription Medicines Code of Practice Authority (PMCPA). The PMCPA was established by the ABPI in 1993 to administer the ABPI Code at arm's length from the ABPI itself.

The pharmaceutical industry is committed to maintaining high standards of professional conduct in the promotion of medicines by acting within both the spirit and the letter of the Code.

The relationship between the PMCPA and the Medicines and Healthcare products Regulatory Agency (MHRA), which is responsible for administering UK law, is set out in a memorandum of understanding (available from the PMCPA). Self regulation is supported by the MHRA and is seen as being the first means of dealing with complaints.

I hope that you will find these guidance notes of assistance in your work. Should you have any queries or require advice please contact the PMCPA (contact details can be found at page 13).

If you have any comments or suggestions as to how the Code could be improved or changed, please send them to the Director of the PMCPA.

Vincent Lawton, President, ABPI

Contents

Why is there a Code of Practice?

The aim of the ABPI Code of Practice[1] is to ensure that the promotion of medicines is carried out in a responsible, ethical and professional manner. The Code incorporates the principles set out in international and European codes and the WHO ethical criteria for drug promotion.

The Code is designed to enable a professional approach to promotion through a self-regulatory mechanism. Companies are expected to respect the spirit, as well as the detail, of the Code. In particular, material must be accurate, balanced, fair, objective and unambiguous, be based on an up-to-date evaluation of all the evidence, and must not mislead (Clause 7.2). Material must be capable of substantiation and substantiation must be provided on request (Clauses 7.4 and 7.5). Companies should not make disparaging remarks about other companies and products or of health professionals and their opinions (Clause 8). High standards are expected at all times (Clause 9.1). A ruling that an activity has brought discredit upon or reduced confidence in the pharmaceutical industry is a sign of particular censure (Clause 2).

What does the Code cover? (Clause 1)

The Code applies to the promotion to UK health professionals and NHS managers of medicines for prescribing, and to information made available to the public about prescription only medicines. It does not cover over-the-counter (OTC) medicines when the object is to encourage purchase by the public. The Code covers meetings for UK health professionals held both within and outside the UK and, in certain circumstances, promotion to UK health professionals at international meetings. International journals which are produced in English in the UK are subject to the Code, even if only a small proportion of the audience is within the UK.

Included in the Code's scope are:

- Journal and direct mail advertising
- Activities of representatives, including detail aids
- Supply of samples
- Provision of inducements, whether in money or kind
- Provision of hospitality for promotional purposes
- Sponsorship of promotional meetings
- Sponsorship of scientific meetings, including payment of travelling and accommodation expenses
- All other sales promotion, including exhibitions, and the Internet

The Code also applies to a number of areas which are non-promotional, including information made available to the public about prescription only medicines.

How are complaints dealt with?

Complaints about any aspect of the promotion of medicines should be sent to the Director of the PMCPA. Complaints can be submitted by anyone. In 2004, out of a total of 119 complaints, 48 were from health professionals (doctors, pharmacists and pharmaceutical/medical advisers) and 46 from pharmaceutical companies, with the majority of the remainder arising from the Director of the PMCPA. Health professionals have an important role to play in monitoring promotional activities and in making complaints in order to maintain the effectiveness of the system. Some complaints give rise to more than one issue, so that in 2004 the Authority considered 424 individual matters, of which 236 were found to be in breach of the Code. More statistics are provided in the PMCPA Annual Report[2].

Complaints are ruled upon in the first instance by the Code of Practice Panel, which is comprised of the Director, Secretary and Deputy Secretary of the PMCPA, taking independent expert 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 at issue pending the final outcome. Similarly, if the Panel rules no breach of the Code, the complainant may appeal. The Appeal Board has an independent, legally qualified Chairman, eight other independent members (mainly health professionals) and twelve senior executives from pharmaceutical companies.

Companies found in breach of the Code have to withdraw the relevant material or cease the activity concerned. They may also be asked to retrieve any literature already circulated or take other appropriate corrective action. They may be subject to an audit of their procedures to ensure compliance and this can be followed by a requirement to submit promotional material to the PMCPA for pre-vetting for a specified period. They can be publicly reprimanded or even suspended or expelled from membership of the ABPI. The Authority advertises in the medical and pharmaceutical press brief details of certain cases of a serious nature. Administrative charges are incurred in every case where a breach is ruled and also when pharmaceutical companies make unsuccessful complaints. No charges whatsoever are payable by complainants from outside the industry. Full reports on completed cases are published in the Code of Practice Review[3]. They are also on the PMCPA website (www.pmcpa.org.uk) which, in addition, gives brief details of ongoing cases.

What controls are there on gifts? (Clause 18)

No gifts may be given to a health professional or manager as an inducement to prescribe, supply, administer, recommend, sell or buy any medicine, except that low value promotional aids may be given that are relevant to the

recipient's work. A low value promotional aid is one that has cost the donor company no more than £6, excluding VAT. The perceived value to the recipient must be similar. Items deemed unacceptable include those for use at home, such as table mats and road atlases. Acceptable items include pens and diaries. Provided that a promotional aid bears no more about the product than the brand or non-proprietary name and the company name, there is no need to include prescribing information.

The Code does not prevent the provision of medical and educational goods and services which will enhance patient care or benefit the NHS while maintaining patient care, providing this is carried out in a way that does not constitute an inducement to prescribe, etc. They must not bear a product name, but may bear a corporate name. The Code includes detailed recommendations for the provision of such services, including that material must be non-promotional and that the relevant NHS trust, etc, is notified. This is particularly important if the services might have knock on effects, such as increasing laboratory work-load.

What controls are there on meetings and hospitality? (Clause 19)

Hospitality must not be provided to health professionals and managers except in association with scientific and promotional meetings or similar. Payment must not be made to doctors or other prescribers for the use of rooms for meetings, although payment can be made to postgraduate medical centres and the like. If meetings are sponsored, this fact should be declared in all relevant documentation such as invitations.

The requirements are:

- Meetings must have a clear educational content
- The venue must be appropriate; lavish or deluxe venues must not be used and venues renowned for their entertainment facilities should be avoided
- Subsistence (meals and drinks) must be secondary to the purpose of the meeting and not out of proportion
- Hospitality must not extend to a spouse or similar unless that person qualifies in their own right as an attendee
- Spouses or similar, unless qualified as above, must not attend the actual meeting or receive, at the company's expense, any associated hospitality

Areas that have caused problems include attendance at social or sporting events, which is usually unacceptable, and overseas meetings. Meetings held outside the UK must have good supporting reasons for being held abroad. Cost saving is, in itself, not seen as sufficient justification for an overseas meeting.

Samples (Clause 17)

A sample is a small supply of a medicine provided to a health professional so that they may familiarise themselves with it and acquire experience of dealing with it. No more than ten samples of a particular medicine may be provided to an

individual during the course of a year. Samples may only be supplied in response to written requests that have been signed and dated, and the company must keep records for at least one year. Samples may only be provided to a health professional qualified to prescribe the product. Samples must be labelled as such, and must be accompanied by a copy of the summary of product characteristics.

A small sample provided only for identification and not intended for treatment may be provided to any health professional but is otherwise subject to the requirements for samples.

The provision of medicines and samples in hospitals must comply with individual hospital requirements.

Starter packs are not covered by these requirements. These are designed for a primary care prescriber to initiate treatment when there might otherwise be an unacceptable delay in commencing treatment. By inference, the range of products covered will be limited to antibiotics, analgesics and the like. The quantity of medicine in the pack has to be modest.

Representatives (Clause 15)

Representatives must not make claims or comparisons which are inaccurate, misleading, disparaging, in poor taste, or outside the terms of the marketing authorization for the product. Representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide appropriate information about the medicines which they promote. They must maintain a high standard of ethical conduct and comply with the Code at all times. Companies must prepare briefing material for representatives on the technical aspects of the medicine and how the product should be promoted.

A key factor for a representative is the handling of appointments with health professionals. They must not use inducements or subterfuge to gain an appointment, and should ensure that the frequency and duration of calls do not cause inconvenience. Payment of a fee for an appointment – even to a charity – is not permitted. Representatives must abide by any arrangements for visits in force in a particular establishment. They must not mislead as to their identity.

At any visit, a representative must have available a copy of the summary of product characteristics for each medicine which they are to promote.

What training is needed for staff? (Clause 16)

All company personnel involved in promotion or in the preparation of promotional material must be fully conversant with the Code. Representatives must take the ABPI representatives examination within one year of commencing employment as a representative and must pass it within two years of commencing such employment. Personnel must be fully conversant with pharmacovigilance requirements relevant to their work.

How is promotional material approved? (Clause 14)

Promotional material must not be issued by a pharmaceutical company unless the final material has been certified by two senior officials of the company, one of whom must be a registered medical practitioner or, in certain circumstances, a pharmacist. The names and qualifications of the nominated persons and any designated alternatives must be notified to the Medicines and Healthcare products Regulatory Agency (MHRA) and to the PMCPA. The certificate must verify that the requirements of the Code have been met and that the material represents a fair and truthful presentation of the facts about the medicine. Material must be re-certified every two years, and certificates must be preserved for not less than three years after the final use of the material and be available for inspection during that time. All promotional material must be certified, including audio-visual and Internet material and representatives' briefing material.

Certification also applies to meetings which involve travel outside the UK. In this case, all of the arrangements must be examined, including the programme, venue, reasons for using that venue, anticipated cost and the nature of the hospitality. It also applies to educational material for the public and patients which relates to diseases or medicines and certain material relating to the provision of medical and educational goods and services.

What information, claims or comparisons can be used in promotion? (Clauses 7 and 9)

Upon reasonable request, a company must promptly provide health professionals with accurate and relevant information on a medicine that it markets. Information, claims and comparisons must be accurate, balanced, fair, objective, unambiguous, be an up-to-date evaluation of all the evidence and must not mislead.

Any claim or information must be capable of substantiation including claims for market share. Such substantiation must be provided without delay at the request of a health professional, including referenced data on file.

The Code gives particular guidance on several aspects of concern. Hanging comparisons, whereby a medicine is described as 'better', 'stronger' etc, without stating what the medicine is compared to, must not be used. The word 'safe' must not be used without qualification. Superlatives can only be used in limited circumstances. The word 'new' should not be used for a medicine or indication which has been available for over twelve months. Graphs and other artwork must not be misleading through, for example, the use of exaggerated scales, and must be labelled so that the information presented can be readily understood. Depictions of children should not be used for products not authorized for use in children in any way that might encourage such use.

Guidance is also included about the use of economic evaluations of medicines.

All material and activities must reflect the special nature of medicines and the professional nature of the target audience. Extremes of format, size, or cost must be avoided. Envelopes and postcards must not carry information which could be seen as advertising. Reply paid cards, for example, may bear either the name of a prescription only medicine or information on its use, but not both.

When does prescribing information need to be included? (Clauses 4, 5 and 18.3)

Prescribing information must be provided in a clearly legible manner in all promotional material, with the exception of abbreviated advertisements and those promotional aids that include no more about the product than the brand or non-proprietary name of the medicine, the name of the company and an indication that the name is a trade mark.

The Code sets out the prescribing information which must be included on each piece of promotional material. When a promotional letter to a health professional accompanies a product brochure, each item must include the prescribing information. The information required includes name(s), indication, dose, side-effects and warnings, cost, legal classification, marketing authorization number and the name and address of the company selling the medicine. Legibility is important, and the Code gives guidance on type size and layout. Guidance is also included on advertisements in electronic journals and on the Internet.

Abbreviated advertisements do not need to include prescribing information, provided that they meet certain requirements. Abbreviated advertisements may only appear in professional publications (not as a loose-leaf insert), are restricted in size, are not allowed in electronic/Internet journals and must comply with a restricted list of contents.

All promotional material, other than promotional aids, must include prominent information about adverse event reporting mechanisms.

Disguised promotion (Clauses 9.10 and 10)

Even if the strict guidance on content of promotional material is followed, care still needs to be exercised in its use. Promotional material must not be disguised such as to resemble editorial material in journals. Market research activities must be such that the collection and analysis of information is kept quite separate from any promotional use to which that information might be put.

Material relating to medicines and their uses, whether promotional in nature or not, which is sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that company.

Distribution of promotional material (Clause 12)

Distribution of promotional material must only be to categories of persons who can reasonably be assumed to have a need or interest in the information, and restraint must be exercised on the frequency of distribution of material. The number of mailings about a particular medicine which can be sent to a health professional each year is specified, as is the number which can be sent in the six months following the launch of a new medicine. Mailing lists must be kept up to date, and requests for removal from a mailing list must be complied with promptly.

Journal advertisements (Clause 6)

An issue of a journal can bear advertising for a particular medicine on no more than two pages.

A loose insert must consist of a single page no larger than the journal page size, printed on one or both sides, and counts towards the two pages allowed.

Does it only cover authorized medicines? (Clause 3)

A medicine must not be promoted prior to it being granted a marketing authorization (licence), and then only in accordance with the terms of the authorization.

Problems can arise if the product has been authorized in another major industrialised country but not in the UK.

The Code therefore includes an exemption for international meetings held in the UK, providing a list of detailed criteria are met. These include that the meeting must be truly international with a significant proportion of attendees from outside the UK.

Another exemption, which relates to the advance notification of new products or product changes, is intended to help NHS managers plan for any significant financial consequence of the introduction of a new medicine. It is appreciated that budget setting may need to take place well before the grant of a market authorization, or indeed before an application has been made. Information can be circulated subject to detailed guidance which includes:

- Information must relate to a new active substance or to a significant addition to the range of authorized indications
- Information must be directed to those responsible for policy decisions on budgets and not to prescribers
- The likely cost and budgetary implications must be indicated and must be such that they will make a significant difference to expenditure
- Only factual information can be presented
- Information should not be promotional in style

Scientific back-up for promotion (Clause 13)

It is a requirement of the Code that companies have a scientific service to compile and collate all information received about the medicines that they market, particularly reports of side effects. This includes dealing appropriately with information fed back from representatives.

Relations with the public and media (Clause 20)

Prescription only medicines must not be advertised to the public, with the exception of vaccination campaigns approved by the health ministers.

Non-promotional information can be provided to the general public directly or indirectly, such as via the media. Such information must be presented in a factual and balanced way and not be designed to encourage patients to ask their health professional to prescribe a specific medicine. Disease awareness campaigns are acceptable, providing the campaign does not promote the use of a specific medicine. Particular care must be taken if there is only one relevant medicine for a condition. Direct enquiries from patients must be answered in a way that does not compromise the patient/prescriber relationship.

Companies can work with patient organisations, including assistance in the provision of information to the public, patients and carers.

A company working with a patient organisation must have in place a written agreement setting out what has been agreed including funding in relation to every significant activity or ongoing relationship. Companies must make public on their websites or in their annual reports lists of all patient organisations to which they provide financial support.

The Internet (Clause 21)

Promotional material on a UK company website or a UK company sponsored website should ideally be access controlled to exclude the public. If this is not done, such a website should provide information for the public as well as promotion for health professionals, with each section separate and clearly identified.

References

1. ABPI Code of Practice for the Pharmaceutical Industry

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PMCPA
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Tel: 020 7930 9677
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www.pmcpa.org.uk

References to all the relevant legal requirements, other codes and guidelines are included in the Code of Practice booklet (page 50)

2. PMCPA Annual Report – available from the PMCPA

3. Code of Practice Review – published quarterly and available from the PMCPA

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