

The International Comparative Legal Guide to:

Pharmaceutical Advertising 2005

A practical insight to cross-border Pharmaceutical Advertising work



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The Self-Regulation of Medicines in the UK

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Introduction

In the United Kingdom, the regulation of advertisements relating to medicinal products is achieved by a combination of statutory measures and self-regulation. The self-regulation element is managed by industry bodies according to the product's legal classification as prescription-only or general sales, and upon the media in which the advertisement or promotion is made. Underpinning the rules of these industry bodies is the legal framework for the control of advertising of medicines which is set out in the Medicines (Advertising) Regulations 1994 (as amended) (the "Advertising Regulations") and the Medicines (Monitoring of Advertising) Regulations 1994 (as amended) (the "Monitoring Regulations").

The Advertising Regulations, which implement European Union Directive 92/28/EC concerning the advertising of medicines for human use (the "Advertising Directive"), prescribe the contents of advertisements for both prescription-only and over-the-counter medicinal products. The Monitoring Regulations set out the procedures for bringing complaints in respect of advertisements which are inconsistent with the Advertising Regulations before the Medicines and Healthcare products Regulatory Authority ("MHRA"). Although the MHRA can refer the matter to the courts, in practice the main force for policing advertisements comes from the industry itself, in the form of the Association of the British Pharmaceutical Industry ("ABPI") with regard to prescription-only products and the Proprietary Association of Great Britain ("PAGB") with regard to the over-the-counter products. Nonetheless, the MHRA itself scrutinises advertising practice, particularly in relation to newly authorised products and where it has cause for concern usually refers the matter to the relevant industry body.

Prescription-only Products

The ABPI manages the advertising and promotion of prescription products under the Code of Practice for the Pharmaceutical Industry (2003) (the "Code") at arm's length through the Prescription Medicines Code of Practice Authority ("PMCPA") which was established in 1993 by the APBI for this purpose.

The Code

The Code applies to the promotion of medicines to health professionals and to information generally available to the public. It does not apply to the promotion of medicines to the public because in the United Kingdom, direct-to-customer advertising of prescription medicines is not permitted under the current legislation. However, the Code does apply to products available over-the-counter (OTC) where the promotional activity in question is designed to encourage issue of a prescription for an OTC medicine. Under the Code, the term 'promotion' is widely defined as including all activities undertaken by a pharmaceutical company which promote the prescription, supply, sale or administration of its medicines. It, therefore, includes, in addition to journal and direct mail advertising, sponsorship of scientific meetings and exhibitions and the promotional activities of the company's representatives when calling on health professionals and printed material used by the representatives in connection with such visits. The aim of the Code is to ensure that the promotion of medicines is conducted in an ethical and responsible manner and, in addition to reflecting the legal requirements controlling advertising, the Code incorporates more general ethical principles set out in international codes, such as the International Federation of Pharmaceutical Manufacturers Association ("IFPMA") Code of Pharmaceutical Marketing Practices. It is directed at ABPI members which are manufacturers and others responsible for promotional activity and at a number of non-ABPI members which have agreed to comply with the Code.

The Code is set out as a series of rules which are drafted both as provisions of general principle to be adopted and more detailed and prescriptive guidelines to be followed. Alongside each rule appears supplementary text giving guidance on practical interpretation derived from experience. In the first instance, no promotion of a medicinal product can take place until the product has been granted a marketing authorisation and when authorised the promotion of the product must be consistent with the details of the product's summary of product characteristics.

All promotional materials must contain prescribing information (in a particular format) and certain additional information such as the marketing authorisation number and the name and address of the marketing authorisation holder. This rule applies to each individual item used in promotion except abbreviated advertisements and certain promotional

aids. All prescribing information must be clear and legible and suggestions as to type size and line length are provided in the Code to assist manufacturers in complying with this requirement. Importantly, the generic (chemical) name for the product or a list of the active ingredients of the product is required to appear in the text immediately adjacent to the most prominent display of the brand name.

The Code deals with information, claims and comparisons made about the product in the promotion and it is alleged breaches of these provisions which occur most frequently in complaints to the PMCPA. In particular, Clause 7.2 prescribes that “*Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or indirectly by implication*”. Therefore, every claim or statement made in promotions must be capable of substantiation and it is a further requirement that the documents supporting all claims and statements be furnished to the health professional upon his or her request without delay.

Comparisons made by the manufacturer of a product claiming the superiority of its products over that of another manufacturer form the basis of much promotional activity in a number of market sectors. In the UK, the acceptability of comparative advertising is not regulated by a single legal source but instead, a complex patchwork of statute, tort and industry codes serves to police the practice. Where the advertising refers to registered trade marks, the Trade Marks Act 1994 allows a manufacturer to refer to another person’s goods so long as the use does not contravene honest practice and is not unfair or detrimental to the distinctive character or repute of the mark. These principles are echoed by the Code under Clause 7.3 which although not precluding the use of other companies’ brand names when making comparisons, requires amongst other things that a comparison is not misleading, is substantiable, does not create confusion and does not take unfair advantage of the reputation or trade mark of the competitor. These principles are re-enforced under Clause 8.1 which states that the products and the activities of other pharmaceutical companies are not to be disparaged, and thereby unjustified knocking copy is strictly prohibited under the Code.

The provisions of the Code apply to the promotional activities of company representatives in equal measure to the promotional materials they disseminate. To ensure compliance, the Code prescribes a list of general principles that must be adhered to by representatives and also requires that all representatives pass the appropriate ABPI examination within two years of taking up such employment. The Code strictly prohibits promotional activity by telephone, fax, email or text messaging except where such material is sent with the prior written consent of the recipient.

To ensure that manufacturers have in place the procedures necessary for their compliance with the Code, all promotional material must be certified by two persons on behalf of the company, that it complies with the regulations of the Code. Of these two persons, one must be a medical practitioner and the other must be a pharmacist or some other suitably qualified person. The names and qualifications of the persons must be notified to the MHRA and PMCPA prior to their exercising this function. In co-

promotion arrangements where two companies jointly promote the same product bearing both of their company names, each company should certify the material as being compliant. In all cases, material which is still in use must be certified at regular intervals of not more than two years and all certificates must be maintained together with essential details as to the recipients of the materials and the mode and date of first dissemination for not less than three years after the final use of the materials.

As stated above, the Code also regulates the sponsorship of meetings. Companies are required to have a written document setting out their policies on meetings and the hospitality provided with such meetings. In all cases, the meetings must have a clear educational content and any hospitality associated with the meeting must be secondary in nature to the purpose of the meeting and must not be of a level as might suggest an inducement to attend.

Similarly, no gifts may be given by a company to a health professional or health administrator as an inducement to prescribe or buy any product.

By way of an example, a recent complaint to the PMCPA was made by a health professional that a pharmaceutical company had paid for UK doctors to attend meetings in various non-UK European locations for a two night stay where the educational section of the meeting lasted for half a day only. The PMCPA concluded that the meetings were unacceptable because of the limited educational content and excessive hospitality and ruled that the company was in breach of the Code (Clause 19 - Meetings and Hospitality) and ruled that such breach was likely to bring discredit upon and reduce confidence in the pharmaceutical industry (a breach of Clause 2 of the Code); a sign of particular censure. In investigating the complaint, the PMCPA was concerned about the certification arrangements for the meetings and decided to conduct an audit of the company’s procedures in relation to the Code.

Administration of the Code

The Code is administrated by the PMCPA in the first instance, by way of the Code of Practice Panel (“Panel”) and on appeal, by the Code of Practice Appeal Board (“Appeal Board”). The Panel comprises the professional staff of the PMCPA who may be assisted from time to time by expert advisors. The members of the Appeal Board are appointed by the Board of Management of the ABPI and include senior executives from pharmaceutical companies (four of whom should be medically qualified), medical members appointed in consultation with the British Medical Association, a pharmacist, a patient representative, one member representing an independent body involved in providing information on medicines and an independent legally qualified chairperson. Complaints made under the Code are forwarded to the Director of the PMCPA who after an initial review of the complaint invites the chief executive of the company concerned, the respondent company, to comment on the matters raised and then decides whether there is a prima facie case. Where the complaint originates from a pharmaceutical company or other entity within the pharmaceutical industry, its identity will be made known but where the complainant is an individual outside the pharmaceutical industry, that person’s identity is kept confidential and only disclosed with his or her express

permission. Where the Director is of the opinion that there is a case to answer, the matter is referred to the Panel which if it finds that the Code has been breached notifies both complainant and respondent accordingly, setting out the reasons for the decision. If the respondent company disputes the decision, it must appeal to the Appeal Board within ten days setting out its reasons. Alternatively, if the respondent accepts the decision, it has ten days within which to provide the Panel with an undertaking signed by the chief executive of the company (or upon his authority) to the effect that the company will discontinue the promotional activity or use of materials complained of and will take all actions to ensure such breaches of the Code are not repeated. The company is required to pay an administrative charge in respect of each breach of the Code.

If the assessment of the Panel is that there is no breach of the Code, both complainant and respondent are informed and where the complainant is a pharmaceutical company, it is required to pay the administrative fee in respect of each issue not in breach of the Code. Similarly, where an appeal to the Appeal Board has been made by the respondent and the Appeal Board finds that there has been no breach of the Code, the complainant pharmaceutical company is required to pay administrative costs based on the number of issues taken to the Appeal Board. Where the Appeal Board finds that there has been a breach of the Code, the respondent company is charged with the payment of these costs. The company must also provide a written undertaking to discontinue such breaches of the Code in the manner described above. Other actions or sanctions that the Appeal Board may enforce include an audit of the company's procedures and, in cases of serious breach, reporting the company to the Board of Management of the ABPI for it to consider further sanctions. The Board of Management may decide:

- to require an audit of the company's procedures as described above;
- to reprimand the company and publish details of the reprimand;
- to require the company to publish a corrective statement;
- to suspend or expel the company from the ABPI; or
- for non-ABPI member companies, to remove them from the ABPI list and inform the MHRA accordingly.

At the conclusion of any complaint a case report is prepared and is disseminated widely including to the MHRA, the Office of Fair Trade, the British Medical Association and the Royal Pharmaceutical Society of Great Britain and are published quarterly by the PMCPA in its Code of Practice Review.

The above description clearly illustrates that the self-regulation procedure offers an efficient and effective means of controlling advertising and promotional activities associated with prescription-only pharmaceuticals without the involvement of the MHRA or legal sanction. However, one case which received much attention in the industry press was resolved following intervention of the MHRA. The case involved Schering Health Care's combined oral contraceptive pill "Yasmin" which was launched in April 2002 with an advertising campaign that claimed "lifestyle" advantages of the product. In particular, the advertisement claimed advantages over similar products with regard to associated weight gain, pre-menstrual symptoms and skin

condition and used the strapline 'The pill for well being'. In support of these claims, the advertisement referenced two clinical research publications. Shortly after product launch, the MHRA (then MCA) conducted a preliminary review of the advertising as part of its monitoring of new products and concluded that the advertising was acceptable.

However, the acceptability of the advertisement was an issue taken up by the Consumer's Association publication, the Drug and Therapeutics Bulletin, which in August 2002 published an article challenging the claims made. Being established practice that media criticism is taken up and dealt with as a formal complaint under the Code, the PMCPA reviewed the Yasmin claims. At the same time, and also prompted by the article, the MHRA re-opened its review of the advertising claims. As a result of the its review, the PMCPA promptly informed Schering Health Care in September 2002, that the advertisement had breached the Code on a number of counts. Schering Health Care then appealed to the Appeal Board but was unsuccessful. The advertisement claims, although substantiated in a number of respects by the referenced publications, were held to be too broad on many counts so as to be misleading and amount to breaches of the Code (Clause 7 - Information, Claims and Comparisons). The case completed on 17 December 2002, but by this date Schering Health Care had already voluntarily withdrawn the advertisement in response to the second review undertaken by the MHRA. Therefore, in this particular case, the intervention by the regulatory authority brought about the resolution of a complaint earlier than that which was likely through the self-regulatory system operated by the PMCPA. However, a full account of the PMCPA proceeding is given in the Code of Practice Review while the deliberations of the MHRA are not published.

This lack of transparency in respect of MHRA reviews of advertisements is now to come to an end and from December 2003, once an investigation into a complaint is complete, the MHRA will post on the relevant section of its website the full details of the complaint and its outcome.

Review of the Code

In 2004 the ABPI announced that it would be conducting a full review of the Code to take into account the changes that have occurred in the pharmaceutical industry since it was last updated.

As part of the review, the ABPI conducted a wide-ranging consultation exercise to enable it to obtain comments about the Code from a large number of individuals and organisations in the industry. The consultation, which ended in March 2005, invited comments on all aspects of the Code, including the overall perception and effectiveness of the Code, how it is applied and enforced, including the efficacy of the sanction it provides, and how the Code might be updated and improved.

One of the particular issues the industry was asked to comment on was the relevance of the Code in light of increased patient involvement in decisions about their treatment.

Completion of the review is expected by the end of 2005, and full details of any amendments to the Code will be provided in next year's guide.

Over-the-Counter Products

The PAGB administers the “PAGB Medicines Advertising Codes - Codes of Practice of Advertising Over the Counter Medicines” that cover the control of advertising of OTC medicines to both consumers and healthcare professionals. There are two codes:

- the PAGB Professional Code (the “Professional Code”); and
- the PAGB Consumer Code (the “Consumer Code”).

Presently, under the Advertising Regulations, advertising to the public is prohibited in respect of products used in preventing, treating or diagnosing certain conditions or disease types. However, an amendment to the Advertising Regulations in 2004 significantly shortened the list of diseases this ban applied to. In addition, the prohibition relating to the remaining diseases - chronic insomnia, diabetes and other metabolic diseases, malignant diseases, serious infectious diseases such as HIV and tuberculosis, and sexually transmitted diseases - will be lifted following 30 October 2005, when recent changes to EU medicines legislation are required to be implemented in the UK.

The Professional Code

The Professional Code was first published in 1994 in response to the Advertising Directive and is used in a manner similar to the Code for prescription-only products, in that it works by consideration of complaints to the PAGB and ongoing monitoring by the PAGB Secretariat of member company promotional activities. It is drafted to conform with the requirements of the Advertising Regulation and compliance with the Professional Code is a condition of PAGB membership.

The Professional Code applies to advertising and promotional activities directed at persons qualified to prescribe or supply medicines and other health workers or retail staff who supply medicinal products directly to the consumer for self-medication. Advertising designed to encourage the prescription of an OTC product is not covered by the Professional Code, but instead is subject to the ABPI Code as discussed above.

As a general principle, advertising should not bring the OTC medicines industry into disrepute nor do anything to prejudice the consumer’s confidence in the industry. An OTC product may not be promoted until it is subject of a marketing authorisation and then only in accordance with the product’s summary of product characteristics.

Under the Professional Code, all claims made in respect of a product must be capable of substantiation and if materials refer to published studies, references must be given to enable confirmation of the claim. Comparative advertising of OTC products is permitted under the Professional Code provided the claims made are capable of substantiation and do not unfairly denigrate or discredit a competitor product. In earlier editions of the Professional Code, reference to the brand names of products belonging to competitor companies was prohibited save in the unlikely situation where that company gave its permission. Now, comparisons between products can be made without first seeking the permission of the product owner, subject to the proviso that the comparison is fair and balanced and accords with the criteria mentioned

above. Hanging comparisons such as “painkiller X gives better pain relief” may not be used under any circumstances, but top parity claims such as “nothing acts faster than painkiller Y” may be used so long as the claim can be substantiated and only for as long as the claim is valid. Clinical superiority claims are permitted provided that they are fully substantiated which means substantiated by direct comparison with all other products on the market and the provision of all available data. Accordingly, such claims are rarely encountered in OTC product advertisements.

The Professional Code prescribes the information to be included in advertisements and which includes the name of the product and a list of the active ingredients placed alongside the most prominent display of the product name, either using the same amount of space as the product name or in font size 10. Regulatory information such as the marketing authorisation number, name and address of authorisation holder, legal status of the product, indication and contra-indications and side effects should be given, together with any warning statements and the price of the product. The advertisement should also incorporate relevant dosage information and, where not bound into a dated publication, the date when all the information was drawn up or revised. Abbreviated advertisements need not contain the price, date, dosage or side effects information but instead should include a statement that further information is available from the marketing authorisation holder.

The Professional Code also covers the promotional activities of company representatives and every company is required to ensure that all of their representatives have sufficient scientific training to enable them to promote the company medicines in a precise and complete manner. Each representative must have available the summary of product characteristics for the products he or she promotes and it must be provided on request to the professional. The Professional Code, in common with the Code of the ABPI, prescribes that any hospitality offered by a pharmaceutical company to a health professional should be of a reasonable level and subordinate to the main purpose or scientific objective of the meeting. Similarly, no gifts or any benefits may be supplied to health professionals unless inexpensive and relevant to the practice of medicine or pharmacy.

Administration of the Professional Code

The Professional Code is administered by the PAGB Secretariat and complaints are dealt with in the first instance by the Complaints Committee, and then if required, the Appeal Board. The Complaints Committee may be assisted by expert advisors when required. The Appeal Board is appointed by the PAGB Executive Director and consists of members of the PAGB Executive Committee, at least one independent pharmacy and/or medical expert depending upon the nature of the complaint and a chairman who should have a legal background or other relevant expertise. The integrity of the Appeal Board is maintained by ensuring that no member has a commercial interest in the complaint to be considered.

When the PAGB receives a complaint that a member may be in breach of the Professional Code, and the complainant is a PAGB member, the PAGB Secretariat will automatically refer the matter for conciliation. If, after going through the conciliation procedure, both complainant and respondent

accept the outcome of the procedure, the matter will not proceed and a brief report is drawn up. If the conciliation procedure fails to resolve the matter, the complaint is considered under the Complaints Procedure. In a similar way, the PAGB Secretariat will seek to resolve complaints by non-PAGB members by means of conciliation before referring the matter to be formally considered under the Complaints Procedure.

Under the Complaints Procedure, complaints received from a pharmaceutical company must be signed by the chief executive officer or person of that company with similar authority, who must specify the clauses of the Professional Code alleged to be breached. Upon receipt of a complaint, if the Complaints Committee is of the opinion that there is no case to answer, both complainant and respondent are informed. The complainant may then seek to appeal the decision, if it so chooses, to the Appeal Board for a final decision. Alternatively, if the Complaints Committee finds that the Professional Code has been breached, the respondent is required to provide an undertaking to the effect that the advertising will be withdrawn or amended, as appropriate. If the respondent does not accept the decision, it too may appeal to the Appeal Board, giving reasons why the Complaints Committee's decision is not accepted. Where the decision is that there has been a breach, the respondent is required to provide a suitable undertaking that the wrong will be remedied as described above and may be required to undergo an audit of its procedures by the PAGB Secretariat.

At the outcome of a complaint, the Complaints Committee drafts a report which is forwarded to the complainant, respondent and Appeal Board for review prior to publication. The final report is sent to the MHRA, the Royal Pharmaceutical Society of Great Britain, the British Medical Association and editors of all major trade press and will also be published on the PAGB website.

The Consumer Code

The Consumer Code, in contrast to the Professional Code and the ABPI Code, operates on a pre-publication clearance basis. The system has been in operation since 1919 and it is a pre-condition of PAGB membership that all advertising aimed at the consumer is submitted in advance to the PAGB to ensure that it complies with the Consumer Code prior to it reaching the consumer. By this means, the industry ensures that all OTC advertising viewed by a consumer not only complies with all legal requirements but also conforms to the principles of taste and decency set out by the Consumer Code. It is important to note that the Consumer Code differs from the Professional Code and the Code in other respects, such as in scope and the principles to be abided by, and these differences reflect the special circumstances involved when promotional activities are directed at the consumer as opposed to a healthcare or retail professional. The PAGB has published guidelines entitled "Guidelines on Advertising by Therapeutic Category" to assist companies in applying the Consumer Code to the various therapeutic categories permitted under the current Advertising Regulations and these should be read in conjunction with the Consumer Code. The Consumer Code does not cover public relations (PR) materials because in these situations, the company rarely has editorial control over the final printed material. However, the PAGB

publishes a separate guideline to assist companies in this area entitled "Guidelines on Consumer Promotions and PR Activities".

PAGB member companies are required to submit all material relevant to the advertising and promotion of their products which includes, in addition to all printed materials and promotion aids, internet materials, cinema commercials, telephone helpline materials and television and radio commercials.

As with the other self-regulatory codes, all advertising under the Consumer Code must be in accordance with the product's summary of product characteristics and should not bring the industry into disrepute. However, in this instance, all advertising must be in a language of a level which can be understood by the average consumer and, although medical terminology is acceptable, it should not be capable of confusing or misleading the consumer. A number of the general principles under the Consumer Code are concerned with the impression that the advertising will convey to the consumer and the possible effect such impression will have on the consumer's treatment of his or her condition. By way of example; the Consumer Code prescribes that advertising should not cause a consumer unwarranted anxiety that he or she is suffering from a condition and should not discourage consumers from seeking medical or pharmacy advice. In addition, advertisements must never suggest that health could be adversely affected if the consumer does not use the products promoted nor that a product's effects are guaranteed. A number of the principles focus on the concept that advertising should not mislead consumers as to the constituents and character of the product, and in particular, the term "natural" may only be used where all the ingredients (both active ingredients and excipients) are naturally occurring and the term "herbal" where all of the product's active ingredients are plants or plant extracts.

The Consumer Code contains more stringent provisions relating to comparative advertising than the other self-regulatory codes. In addition to the usual requirement of substantiation of comparative claims and the prohibition against unfairly denigrating a competitor product, comparative advertising to consumers may not refer to the brand names of other companies without the permission of the brand owner. Neither may advertising suggest that a product's effects are better than or even equal to another identifiable product. In common with the Professional Code, hanging comparisons may not be used in advertisements to consumers and top parity claims and superiority claims are permitted subject to substantiation.

The Consumer Code deals with product endorsement by providing that advertising must not contain a recommendation of a product by scientists or health professionals nor contain the endorsement of celebrities. Testimonials are permitted so long as they comply with the other principles of the Consumer Code, are the genuine views of the user and are less than three years old.

Special reference to children is made under the Consumer Code which forbids advertising directed principally or exclusively at children and requires that no advertisements should show children within reach of medicinal products without the presence of an adult.

Pre-publication Approval

All advertisements in respect of OTC products which are directed at the consumer require the pre-publication approval of the PAGB. Under the procedure advertisements are submitted to the PAGB which checks the contents of the advertisement against the requirements of the Consumer Code, the product's marketing authorisation and any other regulation or code of practice which applies to the medium for which the advertisement is intended. If the advertisement does not conform with the relevant rules and regulations, the company is required to make the necessary changes prior to publication. Once approved, the advertisement may be published but the company must ensure that the advertisement complies with any changes in the law or new guidelines and seek fresh approval from the PAGB where necessary.

The vetting procedure is normally conducted within a 24 hour period but can take a little longer depending upon the type of claims made and the nature of the evidence provided in support of such claims. In some instances, the PAGB may need to seek assistance from medical or legal experts and, in such instances, the review process will be necessarily extended. The PAGB aims to review websites within five working days.

In addition to pre-publication vetting, the PAGB monitors the promotional activities of non-PAGB members to ensure harmonisation of standards in the OTC industry.

Other Self-Regulatory Controls

The ABPI and PAGB Codes usually operate to the exclusion of other self-regulatory mechanisms such as the British Codes of Advertising and Sales Promotion. However, advertising to the consumer may also fall subject to the self-regulatory control of the Broadcasting Advertising Clearance Centre ("BACC") or the Radio Advertising Clearance Centre ("RACC") which are the self-regulatory bodies for television and radio advertising respectively. All television advertising must be cleared by the BACC prior to transmission and similarly all radio advertising must be cleared by the RACC prior to airing. Therefore, OTC product companies must submit their advertisements to one of these bodies (as appropriate) in addition to the PAGB before the advertisement may be put before the consumer.

Conclusion

Although the MHRA has a number of legal sanctions available to it in relation to promotional activity concerning medicinal products, formal legal intervention is highly unusual and very rare. The industry-based self-regulation, although not without its critics, is an undoubtedly highly effective and, to that extent, successful mechanism for ensuring compliance of industry practice with legal and ethical requirements.



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Morgan Lewis

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