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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2004

A practical insight to cross-border Pharmaceutical Advertising work

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Chapter 9

England

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1 General- medicinal products

1.1 What laws and codes of practice govern the advertising of medicinal products in your country?

The advertising of medicinal products in the UK is controlled by a combination of legislation and codes of practice.

There are two principal sets of Regulations implementing the relevant Community provisions: the Medicines (Advertising) Regulations 1994 (SI 1994/1932) and the Medicines (Monitoring of Advertising) Regulations 1994 (SI 1994/1933). Further provisions are set out in Part VI of the Medicines Act 1968. The Medicines and Healthcare Products Regulatory Agency (MHRA) supervises the advertising of medicinal products on behalf of the Health Ministers/Licensing Authority. The Regulations are supplemented by a Guidance Note published by the MHRA.

Control by the MHRA is supplemented by industry Codes of Practice and these Codes provide the real day-to-day control over the advertising of medicines. The Codes have been developed in consultation with the MHRA and are consistent with the legal requirements, while in some cases going beyond them. The Association of the British Pharmaceutical Industry (ABPI) Code of Practice, administered by the Prescription Medicines Code of Practice Authority (PMCPA), governs the advertising of prescription only medicines. The Proprietary Association of Great Britain (PAGB) Consumer Code governs the advertising of over-the-counter medicines to the general public and the PAGB Professional Code governs the advertising of over-the-counter medicines to persons qualified to prescribe or supply.

In addition to the product specific rules, in principle other general legislation may be relevant, such as the Trade Descriptions Act 1968 and the Control of Misleading Advertisements Regulations 1994.

1.2 Must advertisements be approved in advance by a regulatory or industry body before use?

The Regulations do not require the advance approval of all advertising. However, the MHRA has powers under the Regulations to call for copies of advertisements prior to publication. In its Guidance Note, it has indicated that it may exercise these powers in the case of a newly licensed product, or of a reclassified product, or where previous advertising has breached the Regulations. It is also open to companies to seek guidance from the MHRA on proposed advertisements.

The ABPI Code does not require any prior approval for the advertising of prescription only medicines, but again guidance can be sought prior to publication.

In the case of over-the-counter medicines, the procedure depends upon the intended audience. The PAGB Consumer Code requires prior approval. Companies must submit draft advertisements to its secretariat for approval prior to use. However, this requirement does not apply to advertisements caught by the PAGB Professional Code.

1.3 What are the penalties for failing to comply with the rules? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?

The MHRA has the power to issue notices prohibiting the publication of specified advertisements. If it notifies a company that it is minded to consider an advertisement to be in breach of the Regulations, the company has the right to make representations to an Independent Review Panel which gives advice to the MHRA. If the MHRA issues a final notice determining that an advertisement is in breach, the company has no further right of appeal against the notice and will commit a criminal offence if it publishes the advertisement. The company may also be required to publish a corrective statement.

The Regulations create a number of other offences for failing to comply with the relevant Community provisions. Enforcement is by the Enforcement Division of the MHRA. In most cases, a person (including a company) contravening the legislation faces a fine of up to £5,000 per offence if the matter is dealt with by the Magistrates Court. If the matter is dealt with by the Crown Court, there is no statutory maximum fine stated and the Court will impose a higher figure in the case of a serious breach. In addition, a period of up to two years imprisonment may be imposed.

The last time that a pharmaceutical company was prosecuted for an advertising offence was 1988, when both Roussel and its medical director were fined. There

have been no more recent examples, even though the MHRA is becoming increasingly active in raising potential breaches with companies, as there is a preference for resolving complaints quickly and informally.

In the case of a failure to comply with the rules on samples, or the soliciting or accepting inducements by health professionals, the matter must be dealt with by the Magistrates Court and the maximum penalty is a fine of £5,000 per offence.

Under the ABPI Code, a decision is first made by the PMCPA's internal Panel, although there is a right to appeal to a Board consisting of representatives of industry and of the medical profession chaired by an independent lawyer. It is possible for the PMCPA to impose an administrative fine (£1,000 or £4,000 if the matter is unsuccessfully appealed). The Authority also has the power in serious cases to require an audit of a company's promotional procedures, or to suspend or expel the company from the ABPI.

The PAGB does not impose any financial sanctions, but where a company has failed to comply with the Code, it may be expelled from the PAGB.

Generally it is not usual for competitors to take direct action through the courts, although they can make complaints to the MHRA, PMCPA and PAGB. It would only be possible in the case of an action based on defamation, slander of goods or an infringement of trade mark rights. There is no unfair competition statute that provides a ready basis for a complaint.

2 Providing information prior to authorisation of medicinal product

2.1 To what extent is it possible to make information available to health professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product?

Regulation 3 of SI 1994/1932 (Clause 3 of the ABPI Code) states that no person may issue an advertisement for a medicinal product which does not have a marketing authorisation.

On the other hand, it is possible to discuss unlicensed medicines at genuine scientific meetings, where the tone of the discussions is not promotional. This is possible even if a company is sponsoring a meeting, provided that the discussions amount to a legitimate scientific exchange of information.

It is not possible for companies to display information about unlicensed medicines at such meetings, but they may make scientific information available at the request of delegates. They must not, however, solicit such requests.

Clause 3 of the ABPI Code sets out special rules for the promotion of medicines at international meetings taking place in the UK. Where these are truly international meetings of high scientific standing with a significant proportion of attendees from outside the UK, it is possible to display information upon medicines which are not authorised in the UK but authorised in at least one other major industrialised country.

2.2 May information on unauthorised medicines be published? If so, in what circumstances?

Information of genuine scientific interest which is not promotional may be published. If the publication has been sponsored by a pharmaceutical company, the fact of sponsorship must be clearly indicated.

2.3 Is it possible for companies to issue press releases about medicinal products which are not yet authorised? If so, what limitations apply?

It is possible to issue press releases to both professional and general audiences, provided that the releases concern a matter of legitimate scientific interest (for example, the results of a pivotal clinical trial) and that they are not promotional in tone. For example, the trade name should be used in moderation and sweeping claims should not be made.

2.4 May such information be sent to health professionals by the company? If so, must the health professional request the information?

Such information may only be sent to a health professional if it has been requested by him. The company must not encourage him to make such a request. Ideally such a request should be channelled through the medical information department, rather than via sales and marketing.

2.5 May information be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

The APBI Code of practice makes express provision for this (Clause 3.1), provided that certain conditions are complied with. In particular, the new medicine must have significant budgetary implications, the information must be directed towards those responsible for budgets and only factual information must be given.

3 Advertisements to health professionals

3.1 What information must appear in advertisements directed to health professionals?

Regulation 14 of SI 1994/1932 (Clause 4 of the ABPI Code) states that, with the exception of audio-visual advertisements and abbreviated advertisements, all advertisements to health professionals must contain essential information compatible with the SmPC and must contain the following:

- Marketing authorisation number
- Name and address of marketing authorisation holder
- Supply classification of product
- Name of medicinal product and list of active ingredients immediately adjacent to the most prominent display of the name
- One or more indications for use consistent with the terms of the authorisation
- Succinct statement of entries in SmPC relating to side-effects, cautions and relevant contra-indications
- Succinct statement of entries in SmPC relating to dosage, method of use and method of administration (where not obvious)
- Any warning which the licensing authority requires being included

- The cost of the product

Regulation 15 contains special rules for audio-visual advertisements. These must contain essential information compatible with the SmPC and refer to the particulars listed in paragraphs 1-8 above. However, those particulars may be contained in written material made available to those viewing the advertisement.

Regulation 16 sets out special derogations for "abbreviated advertisements" (advertisements no larger than 420 square centimetres contained in a publication sent or delivered to health professionals). Such advertisements must contain essential information compatible with the SmPC and also the following:

- Name and address of marketing authorisation holder
- Supply classification of product
- Name of medicinal product and list of active ingredients immediately adjacent to the most prominent display of the name
- A form of words which indicates that further information is available on request, or in the SmPC

Regulation 17 states that the requirements in regulations 14, 15 and 16 do not apply in the case of an advertisement which is a promotional aid if the advertisement consists solely of the name of the product and is intended solely as a reminder. The MHRA has indicated that this provision is intended to cover items such as pens, notepads and mugs.

Further guidance is set out in the ABPI Code: Clause 4 (legibility and type size) and Clause 6 (journal advertising).

These rules also apply to international journals where these are produced in English in the UK (even if only a small proportion of their circulation is to a UK audience) and/or intended for a UK audience.

3.2 What rules govern comparator advertisements? Is it possible to use another company's brand name as part of that comparison?

Comparator advertisements are permitted, provided that these are fair and balanced and do not mislead (Regulation 3A of SI 1994/1932; Clause 7 of the ABPI Code). In such a case, it is possible to use another company's brand name without its permission, provided that no unfair advantage is taken of the reputation of the brand name or the other company.

3.3 Are "teaser" advertisements permitted, which alert a reader to the fact that information on something new will follow (without specifying the nature of what will follow)?

Such advertisements are prohibited in the UK by Clause 9 of the ABPI Code (although they are not referred to in the Regulations).

4 Gifts and financial incentives

4.1 Is it possible to provide health professionals with samples of products? If so, what restrictions apply?

Under Regulation 19 of SI 1994/1932 (Clause 17 of the ABPI Code), free samples are permitted, provided certain conditions are met. Samples must only be provided to persons qualified to prescribe medicinal products and they must be provided to enable those persons to acquire experience in dealing with the product. No samples of controlled products may be supplied. In addition:

- Samples must be supplied on an exceptional basis only
- A limited number of samples of each product may be supplied in any one year to any one recipient (the ABPI Code states that this should not exceed ten samples)
- Samples must only be supplied in response to a written, signed and dated request
- The supplier must maintain an adequate system of control and accountability
- Samples must be no larger than the smallest presentation available for sale
- Samples must be marked with wording indicating that they are free medical samples and are not for resale
- A copy of the SmPC must accompany samples

4.2 Is it possible to give gifts or donations of money to medical practitioners? If so, what restrictions apply?

This is possible in very limited circumstances under Regulation 21 of SI 1994/1932 (Clause 18 of the ABPI Code). In the case of gifts, these must be inexpensive and relevant to the recipient's work.

The ABPI Code provides further guidance. Gifts must not cost the donor company more than £6. Donations of money are not permitted, although donations to reputable charities may be permitted provided that such donations are not offered in return for granting interviews with medical representatives.

It is possible to offer gifts of a greater value (but still relevant to the practice of medicine or pharmacy) as prizes in competitions involving skill. Such prizes must be limited in number, relevant to the recipient's work and have a maximum cost to the donor of £100.

In addition, the National Health Service has published general Guidelines on Commercial Sponsorship setting out ethical standards which all health professionals must observe. For example, National Health Service staff and contractors must refuse to accept gifts, benefits, hospitality or sponsorship of any kind which might reasonably be seen to compromise their personal judgement or integrity. In addition, gifts, benefits and sponsorships must be declared in a register.

4.3 Is it possible to give gifts or donations of money to institutions such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

The ABPI Code states that this is possible where the gift or donation is intended to enhance patient care or benefit the National Health Service. However, such a gift or donation must not be offered as an inducement to prescribe or use any particular medicine. Items donated may bear the company name, but cannot bear a product name. Clause 18.1 of the Code contains detailed guidelines on the provision of goods and services to the National Health Service. For example, it is possible for a company to sponsor a nurse, but the recipient of the service must be provided with a written protocol setting out the details of the arrangement and the nurse must not be used to promote the company's products.

4.4 Do the rules on advertising and inducements permit the offer of a volume related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

Both the Regulations and the APBI Code state that measures or trade practices relating to prices, margins and discounts are permitted, provided that these are of a type that was in regular use by a significant proportion of the pharmaceutical industry in the UK on 1 January 1993. No official guidance is available on precisely what arrangements would qualify.

4.5 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?

This is not possible.

4.6 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed?

Such arrangements are highly unusual, as in each case it will be necessary to demonstrate that there is no element of inducement. However, the concept of risk-sharing between the industry and the Department of Health/ National Health Service has been accepted in certain circumstances. There is currently a scheme in operation for disease modifying therapies for multiple sclerosis. Under the scheme, the cost of the medicine to the National Health Service is reduced if the product fails to achieve specified target outcomes.

It would not be possible to operate any such scheme for an over-the-counter medicine purchased by a consumer.

5 Hospitality and related payments

5.1 What rules govern the offering of hospitality to health professionals?

This is governed by Regulation 21 of SI 1994/1932 (Clause 19 of the ABPI Code). Hospitality must be reasonable and secondary to the scientific purpose of a meeting. Nobody other than a health professional may be offered hospitality. The Code states that exceptionally, it may be possible to offer hospitality to appropriate administrative staff, but it is not possible, for example, to include spouses (unless they are also health professionals).

The rules apply equally to UK doctors offered hospitality overseas.

5.2 Is it possible to pay for a doctor in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

According to the guidance in the ABPI Code, it is possible to pay reasonable actual travel, accommodation and enrolment costs to enable a delegate to attend a scientific meeting. It would not be possible to pay a delegate for his time. If the delegate is also a speaker, however, a reasonable honorarium may be paid.

5.3 Is it possible to pay doctors to provide expert services (e.g. participating in focus groups)? If so, what restrictions apply?

It is possible to pay doctors to provide expert services, including travel costs and payment for time spent attending meetings. However, the meetings must have a genuine scientific content and must not be promotional in tone. The number of doctors involved in such activities must be limited and there must be an objective reason linked to their interest or expertise for including them.

6 Advertising to the general public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Non-prescription medicines may be advertised to the general public. Regulation 9 of SI 1994/1932 sets out certain conditions which must be complied with. The advertisement must not:

- Give the impression that a medical consultation is not necessary
- Suggest that the effects of the medicine are guaranteed, without side effects, or better than or equivalent to another medicine or treatment
- Suggest that taking the medicine will enhance health
- Suggest that health may be adversely affected by not taking the medicine
- Be directed to children
- Include a recommendation by a health professional or well known person if this could encourage the consumption of the medicine
- Suggest that the product was a food, cosmetic or other consumer product
- Suggest that the safety or efficacy of the product was due to its natural status
- Might, by use of a case history, lead to erroneous self-diagnosis
- Refer in improper, alarming or misleading terms, to claims of recovery
- Use improper, alarming or misleading representations of the human body
- Mention that the product has a marketing authorisation

Further guidance on the interpretation of these provisions is contained in the PAGB Code.

6.2 Is it possible to advertise prescription only medicines to the general public? If so, what restrictions apply?

This is prohibited by Regulation 7 of SI 1994/1932.

6.3 If it is not possible to advertise prescription only medicines to the general public, are disease awareness campaigns permitted, encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Guidance on this issue had been provided by the MHRA and by the ABPI (Clause 20 of the Code).

Non-promotional information may be made available in certain circumstances, provided it is factual and balanced. Statements must not be made for the purpose of encouraging members of the public to ask their doctors to prescribe a particular medicine.

European public assessment reports, summaries of product characteristics and package leaflets may be provided on request.

Disease awareness campaigns are permitted and the MHRA has issued a specific guidance note on this subject. It is important that the purpose of the campaign is to increase awareness of a disease and to provide health education information on that disease and its management. While it may involve the discussion of treatment options, it must not promote the use of a particular medicinal product. Disease awareness campaigns where there is only one treatment option, or only one medicine in a particular class, require particular care.

Information on prescription only medicines may also be provided to financial institutions and share-holders, provided it is factual and balanced.

6.4 Is it possible to issue press releases concerning prescription only medicines to non-scientific journals? If so, what conditions apply?

This is possible, provided the information is of genuine scientific interest and not promotional in tone. It must not encourage members of the public to ask their doctor to prescribe a particular product. Use of the brand name should be kept to the minimum.

7 The Internet

7.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

The same rules apply as for other forms of advertising. As a matter of practice, enforcement remains an issue as far as the regulators are concerned, as they are only able to enforce against entities with a presence in the jurisdiction.

Clause 21 of the ABPI Code states that the PMCPA will take action where the advertising has been placed on the internet by or with the authority of a UK company and makes reference to use or availability of a product in the UK. The PMCPA has upheld a small number of complaints under this provision.

7.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for health professionals?

It is necessary to have proper password security, where the code is known only to doctors. A simple tick box option asking whether the person is a doctor is not sufficient. On the other hand, it is acceptable to ask a doctor to provide his surname and General Medical Council Registration number, even though it is theoretically possible for a member of the public to obtain this information.

8 General- medical devices

8.1 What laws and codes of practice govern the advertising of medical devices in your country?

There are no specific laws or codes relating to the advertising and promotion of medical devices. Promotion would, however, be subject to the general laws on advertising and promotion, including the Control of Misleading Advertisements Regulations 1994.

Comparative claims are generally allowed, provided that they are objective and do not mislead. Brand names of competitors may be used. If an advertiser fails to comply with the Regulations, the Director General of Fair Trading may obtain an injunction to prevent the further publication of the misleading advertisement.

In the case of an advertisement referring to the merits of a device used for administering medicines, such as an inhaler, even if no particular medicine is mentioned Clause 4.1 of the ABPI Code states that the advertisement must include prescribing information relating to at least one medicine.

In addition, the Trade Descriptions Act 1968 makes it a criminal offence to issue a false or misleading trade description.

8.2 Are there any restrictions on payments or hospitality offered to doctors in connection with the promotion of a medical device?

There are no specific rules. Again, the National Health Service Guidelines on Commercial Sponsorship will determine what a medicinal professional may accept.

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ARNOLD & PORTER (UK) LLP

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