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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2013

10th Edition

A practical cross-border insight into pharmaceutical advertising

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■ **Preface** by Tom Spencer, Counsel, GlaxoSmithKline Plc.

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1 General - Medicinal Products

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

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

The main regulations are found in Part 14 of the Human Medicines Regulations 2012/1916 (the Regulations). The Medicines and Healthcare products Regulatory Agency (MHRA) supervises the advertising of medicinal products on behalf of the licensing authority. The Regulations are supplemented by guidelines published by the MHRA: The Blue Guide - Advertising and Promotion of Medicines in the UK, August 2012.

Control by the MHRA is supplemented by industry Codes of Practice, which provide the most detailed and immediate control over the advertising of medicines. The Association of the British Pharmaceutical Industry Code of Practice (the ABPI Code), administered by the Prescription Medicines Code of Practice Authority (PMCPA), governs the advertising of prescription-only medicines (POM); the latest version came into operation on 1 July 2012. 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. The Codes of Practice repeat the law, but in several respects, go beyond it.

In addition to the controls on medicines, in principle, other general legislation may be relevant, such as the Trade Descriptions Act 1968. Commercial practices (including advertising) relating to consumer goods are subject to a series of laws on trading of consumer goods, including the Consumer Protection from Unfair Trading Regulations 2008/1277 (business-to-consumer practices) and the Business Protection from Misleading Marketing Regulations 2008/1276 (business-to-business practices).

1.2 How is "advertising" defined?

"Advertisement" is defined in section 7 of the Regulations as "anything designed to promote the prescription, supply, sale or use of [a medicinal] product". This includes: door-to-door canvassing; visits by medical sales representatives to persons qualified to prescribe or supply medicinal products; the supply of samples; the provision of inducements to prescribe or supply medicinal products by the gift; offer or promise of any benefit or bonus, whether in money or in kind (except where the intrinsic value is minimal); the sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products; and the sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products, including payment of expenses.

The Regulations exclude from this definition: packaging; correspondence answering specific questions about a medicinal product; and reference material and announcements of a factual and informative nature including: (i) material relating to changes to a medicinal product's package or package leaflet; (ii) adverse reaction warnings; (iii) trade catalogues; and (iv) price lists, provided that no product claim is made.

The ABPI Code does not define "advertising", but does define "promotion", which is not different in principle. This covers "any activity undertaken by a pharmaceutical company or with its authority that promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines" (Clause 1.2).

The Court of Justice of the European Union (CJEU) has clarified the definition of advertising and the persons subject to EU advertising rules. In particular, Article 86(1) of Directive 2001/83/EC (the Directive) provides a definition of advertising that focuses on the purpose of the message and the objective pursued, i.e. if the intention is to promote the prescription, supply, sale or consumption of medicinal products, it is advertising (C-316/09 MSD). It is not necessary for the message to be disseminated by a person linked to the manufacturer and/or seller of the medicinal product or to be disseminated in the context of commercial or industrial activity in order for it to be held to be advertising (C-421/07 *Damgaard*). However, the prohibitions, for example, in relation to the provision of financial inducements, do not apply to national authorities pursuing public health policy, including any policy on the public expenditure on pharmaceuticals (C-62/09 ABPI).

The dissemination of information that is a faithful reproduction of the approved package leaflet or summary of product characteristics (SmPC) of a medicinal product is unlikely to be considered advertising, although the selection, manipulation or rewriting of any such information can likely only be explained by an advertising purpose (C-249/09 *Novo Nordisk*).

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

Companies should make sure that all staff involved in promotion are trained on the ABPI Code. Although companies may have

different internal procedures and guidelines for reviewing material, promotional material must not be issued unless its final form has been certified by two persons on behalf of the company. One of the two persons should be a registered medical practitioner or a registered pharmacist (or a registered dentist if the product is for dental use only). The second person must be an appropriately qualified person or senior official of the company or an appropriately qualified person whose services are retained for that purpose.

The following materials must be certified in a similar manner (although one of the persons certifying must be a registered medical practitioner, or, in the case of a product for dental use only, a dentist): (i) educational material for the public or patients issued by companies that relates to disease or medicines, but is not intended as promotion for those medicines; (ii) material relating to working with patient organisations; (iii) material prepared in relation to joint working between the NHS and the pharmaceutical industry; (iv) material relating to patient support programmes involving the provision to health professionals of items to be passed on to patients; and (v) non-promotional material for patients or health professionals relating to the provision of medical and educational goods and services issued by companies. Material that is still in use must be recertified at intervals of no more than two years. Certificates and accompanying material must be retained for at least three years after the final use of the material.

Companies must have a scientific service to compile and collate all information issued or received from any other source about the medicines they market.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities? If so, what aspects should those SOPs cover?

There are no legal requirements for companies to have specific SOPs. The ABPI Code includes a section on "Guidelines on company procedures relating to the code of practice". These guidelines provide that in order to assist with compliance, companies should have a comprehensive set of SOPs covering all aspects of the ABPI Code. SOPs should set out high standards and companies are expected to ensure that relevant staff are trained on their content. The guidelines require pharmaceutical companies to have written documents setting out the representatives' instructions on the application of the ABPI Code to their work, and a written document that sets out their policies on meetings and hospitality and the associated allowable expenditure.

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

The Regulations do not require the advance approval of advertising. However, the MHRA has the power under section 304 of the Regulations to issue a notice requiring a marketing authorisation holder to supply copies of advertisements prior to publication and not to use those advertisements until they have been approved. It is a criminal offence to fail to comply with such a notice. Pre-use vetting is usually requested in the following circumstances: (i) where a newly licensed product subject to intensive monitoring is placed on the market; (ii) where a product is a reclassified product, for example, from prescription-only to pharmacy; or (iii) where previous advertising for a product has breached the Regulations. Pre-use vetting may also be requested as a result of a major new indication for use or where there are safety concerns. In addition, the MHRA has committed to vetting initial advertising for all new active substances.

The duration of the vetting is commonly one to three months, and does not normally extend for longer than six months. This period can be reduced or extended depending on the quality of the initial advertising material submitted and other relevant factors. Information on the target audience should be included, as well as references in support of claims made.

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 POMs, but again, guidance can be sought prior to publication.

In the case of over-the-counter medicines, the PAGB Consumer Code requires prior approval. However, this requirement does not apply to advertisements aimed at persons qualified to prescribe or supply medicines, or their employers (caught by the PAGB Professional Code).

1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

The MHRA has the power, under sections 304, 305 and 306 of the Regulations, 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 written representations to the Independent Review Panel for Advertising, 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 and will commit a criminal offence if it publishes the advertisement. The company may also be required to publish a corrective statement.

While there is no appeal mechanism, it is open to the company to challenge the legality of a notice by means of judicial review. In practice, this is likely to be unsuccessful, unless the Panel's procedure was procedurally unfair.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? 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?

Enforcement is by the Enforcement & Intelligence Group of the MHRA. In most cases, a person (including a company) who contravenes 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, and the Court will impose a higher figure in the case of a serious breach. In addition (or alternatively), a period of up to two years' imprisonment may be imposed.

Prosecutions for advertising offences are extremely rare. Past prosecutions for illegal advertising do not relate to advertising activities addressed to healthcare professionals, but rather to

products that are claimed to have medicinal properties, but that are not authorised as medicines, or to advertising to the general public of POMs via the Internet or otherwise. The MHRA prefers to resolve complaints quickly and informally, with companies agreeing to take voluntary action to amend their advertising and, in some cases, to issue a corrective statement. Details of cases resolved informally are posted on the MHRA's website.

Under the ABPI Code, a decision is first made by the PMCPA's internal Panel, and there is a right to appeal to a Board consisting of representatives of industry, of the medical profession and independent members (who will form a majority) chaired by an independent lawyer. Administrative charges are payable when a company is found in breach of the ABPI Code (£3,000 per matter for ABPI member companies, or £11,000 if the matter is unsuccessfully appealed). The Panel 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 sanction, but a company may be expelled from the PAGB if it has failed to comply with the PAGB Code.

Generally, it is unusual for competitors to take direct action through the courts, although they can make complaints to the MHRA, PMCPA and PAGB. Legal proceedings by companies are only possible in the case of an action based on defamation, slander of goods or an infringement of trade mark rights (see question 1.9).

1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can, and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

The relationship between the self-regulatory process, administered by the PMCPA, and the supervisory and enforcement function of the competent authority, the MHRA, is set out in a Memorandum of Understanding between the two bodies and the ABPI. The two systems are regarded as "complementary and synergistic", but the self-regulatory system does not oust the jurisdiction of the MHRA. Both bodies can hear complaints from whatever source, save that the MHRA would normally refer inter-company complaints to the PMCPA to deal with, and may refer other complaints to the PMCPA with the consent of the complainant. The MHRA will routinely decline to investigate cases where it is aware that these are under investigation by a self-regulatory body, but reserves the right to take action if serious public health concerns are raised or if self-regulation fails (e.g. if the sanctions imposed by a self-regulatory body do not seem to deter a company from committing further material breaches of the rules). It is possible that material pre-vetted and approved by the MHRA might subsequently be ruled by the PMCPA as in breach of the ABPI Code. The MHRA regularly reviews information on the PMCPA website about the consideration of current cases and may investigate the case further when the PMCPA proceedings are completed. To date, there have been no prosecutions by the MHRA following adverse findings of the PMCPA.

1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

UK legislation does not create a separate offence of unfair competition. Setting aside breach of the advertising rules, there is the option of taking action based on trade mark law, passing off or trade libel. A trade mark infringement action may be brought by the owner of the trade mark that has been infringed. A passing off action may be brought by a party whose goods are being misrepresented as the goods of another party, provided the party in question can show sufficient goodwill in the name of the product and such actions lead to a misrepresentation that causes damage. A trade libel action may be brought by a trading corporation or company whose reputation in the way of its trade or business is damaged.

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? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product's variants not authorised)?

Section 279 of the Regulations (reflected in Clause 3 of the ABPI Code) states that no person may issue an advertisement for a medicinal product that does not have a marketing authorisation (or a traditional herbal registration, a registration for homoeopathic medicinal products or an "Article 126a authorisation" (authorisations justified for public health reasons)).

The supply of unlicensed medicinal products for individual patients in the UK is governed by Part 10 of the Regulations. Section 167 permits supply of unlicensed products in certain circumstances and if certain conditions are met. The conditions include a requirement "that no advertisement relating to the medicinal product is published by any person".

It is possible to discuss research concerning unlicensed medicines at genuine scientific meetings, provided neither the content nor the tone of the discussions appears designed to promote the use of the product, but is merely informing the audience of new scientific knowledge and encouraging a legitimate exchange of scientific information. This is possible even if a pharmaceutical company is sponsoring the meeting.

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. Companies must not, however, solicit such requests.

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

The position is the same regarding the provision of off-label information.

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

Information of genuine scientific interest that 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 are not promotional in tone. For example, the trade name should be used in moderation and sweeping claims should not be made. The tone and content must be accurate, factual and balanced.

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

Upon request, such information can be provided to healthcare professionals. Any activity that appears to be designed to solicit such requests is likely to be considered to be promotional.

2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in the UK?

Following the decision in Case C-143/06 *Ludwigs*, the legislation in force at the time was amended to allow the provision of price lists for unlicensed products. This is retained in section 7 of the Regulations that excludes price lists from the definition of advertisement. The ABPI Code clarifies that price lists relating to unlicensed medicines are not considered as promotion provided that they include no product claims, and make clear that the products are unlicensed. Such price lists can be sent to health professionals and appropriate administrative staff at reasonable intervals or in response to enquiries, and without first having received an unsolicited order. They must not be used proactively in a manner that could be seen to be promoting unlicensed medicines, such as by displaying them on exhibition stands.

The MHRA has advised that any price list supplied should only consist of a basic line listing providing the following information: reference number; medicinal product name (British-approved name or equivalent); dosage form; strength; pack size; and price.

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

The ABPI Code expressly allows this, provided that certain conditions are met. In particular: the new medicine must represent a significant development (e.g. contain a new active substance or have a novel and innovative means of administration), and have significant budgetary implications; the information must be directed only towards those responsible for budgets and not to prescribers; and it must be limited to factual material. The information must not be in the style of promotional material. MHRA Guidance also acknowledges that such information may be provided "exceptionally".

2.7 Is it possible for companies to involve health professionals in market research exercises concerning possible launch materials for medicinal products as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

Under the ABPI Code, market research is defined as the collection and analysis of information, and must be unbiased and non-promotional. The use made of such information and statistics may be promotional, but these two phases must be kept distinct. It is acceptable to enter into agreements with health professionals for *bona fide* consulting services, including market research activities. It would, in principle, be possible to conduct market research exercises concerning launch materials for products as yet unauthorised, but it is not permitted to use such activities as a platform for disguised promotion to health professionals. In this regard, it is crucial to define the objective of the market research, which will decide the number of healthcare professionals that it is reasonable to involve. Any materials used should be strictly non-promotional. It is preferable to use generic names where possible.

The British Healthcare Business Intelligence Association has produced guidelines on market research in consultation with the ABPI entitled "The Legal and Ethical Framework for Healthcare Market Research".

3 Advertisements to Health Professionals

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

Section 294 and Schedule 30 of the Regulations (reflected in Clause 4 of the ABPI Code) states that, with the exception of 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 medicinal product.
- Name of medicinal product.
- 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 (i) adverse reactions, precautions and relevant contra-indications, (ii) dosage and method of use, and (iii) the method of administration (where not obvious).
- The cost of the product.
- Any warning that the licensing authority requires to be included.

Section 295 sets out special derogations for "abbreviated advertisements" (advertisements no larger than 420 square centimetres, that appear in a publication sent or delivered to health professionals). Such advertisements must contain essential information compatible with the SmPC and the majority of the information required for a full advertisement. However, abbreviated advertisements differ in that the detailed prescribing information is provided on a website rather than in the advertisement.

Section 296 states that these requirements do not apply in the case of an advertisement that is a promotional aid if the advertisement

consists solely of the name of the product or its international non-proprietary name or trade mark (in the case of a registered homoeopathic medicinal product, this could also be the scientific name of the stock or stocks or its invented name), and is intended solely as a reminder.

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 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not in the SmPC?

In Case C-249/09 *Novo Nordisk*, the CJEU concluded that Article 87(2) of the Directive prohibits the inclusion in advertising of claims that conflict with the SmPC. However, not all the information contained in an advertisement needs to be identical to that in the SmPC, provided the claims are consistent with the information in the SmPC. Advertisements may, therefore, include additional claims, provided that these confirm or clarify (and are compatible with) the information set out in the SmPC. Any such additional information must also meet the various other requirements of the Directive, such as being presented objectively, faithfully and in such a way as to allow independent verification, and not being exaggerated, misleading or inaccurate. This reflects current practice in the UK. Clause 3.2 of the ABPI Code states that the promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its SmPC.

3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

Section 289 of the Regulations prohibits the issue of advertisements wholly to mainly directed at members of the public that refer to recommendations by scientists, healthcare professionals, or persons who because of their celebrity, could encourage the consumption of medicinal products. This limitation does not apply to advertisements directed to healthcare professionals.

3.4 Is it a requirement that there be data from any or a particular number of "head to head" clinical trials before comparative claims are made?

Controlled 'head to head' clinical trial data are not required to substantiate comparative claims, although the availability of such data will inevitably assist in demonstrating that statements are balanced and can be substantiated. Presentations of weak comparative data from individual studies may be judged misleading and all relevant data must be presented to ensure a fair and balanced comparison. Differences that do not reach statistical significance must not be presented in such a way as to mislead. Before statistical information is included in promotional material, it must have been subjected to statistical appraisal.

The MHRA has advised that, where secondary end-points are being used to promote a product, primary end-point data and the limitations of the data must be included.

3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product which had not yet been authorised in the UK?

Comparator advertisements are permitted provided they are accurate, fair, balanced, objective, unambiguous, based on an up-to-date evaluation of the evidence and reflect the evidence clearly (Clause 7 of the ABPI Code). 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. Disparaging references to other products are prohibited (Clause 8 of the ABPI Code).

Advertising material referencing a competitor's product, which has not been authorised in the United Kingdom, may be characterised as promoting an unlicensed medicine contrary to section 167 of the Regulations and Clause 3 of the ABPI Code.

3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to doctors?

The distribution of conference proceedings, abstract booklets, meeting reports or a slide set following a scientific congress or conference may constitute promotion depending on the circumstances and the content of such information. To the extent such information relates to a medicinal product, provision on an unsolicited basis may constitute a promotional activity and, therefore, the general requirements regarding promotional materials should be complied with.

Reprints of articles in journals that have not been refereed must not be provided unless in response to a request. Placing documents on exhibition stands amounts to an invitation to take such materials, i.e. it solicits the request. When providing an unsolicited reprint of an article about a medicine, it should be accompanied by prescribing information (Clause 10.1 of the ABPI Code).

All material relating to medicines and their uses, whether promotional or not, that is sponsored by a pharmaceutical company, must identify that fact sufficiently prominently so that the reader or recipient is aware of the position from the outset (Clause 9.10 of the ABPI Code).

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

While there is no specific reference to such advertisements in the Regulations, they are prohibited by Clause 9 of the ABPI Code.

4 Gifts and Financial Incentives

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

Under section 298 of the Regulations (reflected in Clause 17 of the ABPI Code), free samples are permitted, provided certain conditions are met. In particular, samples must only be provided to persons qualified to prescribe medicinal products, and must be provided to enable those persons to acquire experience in dealing with the product. They must not be provided as an inducement to prescribe or supply any medicine.

In addition:

- Samples must be supplied on an exceptional basis only.

- Samples must only be supplied in response to a written, signed and dated request.
- No more than four samples of a new medicinal product may be supplied in any one year to any one recipient.
- Samples of a new medicinal product can only be provided for no longer than two years after the healthcare professional first requests that sample.
- 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.
- The supplier must maintain an adequate system of control and accountability.
- No samples of controlled products may be supplied.
- Samples distributed by medical representatives must be handed directly to healthcare professionals, or a person authorised to receive them on their behalf.

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

The provision of gifts is possible in limited circumstances under section 300 of the Regulations: if they do not constitute an inducement to a healthcare professional to prescribe or supply any medicine, and they are inexpensive and relevant to the recipient's work.

The ABPI Code prohibits many of the traditional forms of promotional aids, such as coffee mugs and calendars, items for use in clinics such as surgical gloves or tissues, or toys and puzzles for children (Supplementary Information to Clause 18.1). The only promotional items expressly permitted are inexpensive notebooks, pens and pencils for use by health professionals and appropriate administrative staff attending scientific meetings, conferences and promotional meetings. Such promotional aids must not bear the name or any information about any medicine, but may bear the name of the company providing them.

Items intended to be passed to patients can be provided to health professionals if they are part of a patient support programme, the details of which must be appropriately documented and certified in advance. They must cost no more than £6, excluding VAT, and the perceived value to the health professional and the patient must be similar. They must directly benefit patient care.

Donations of money to medical practitioners are not permitted, although donations to reputable charities may be acceptable provided that any associated action required of the healthcare professional is not inappropriate (e.g. the offer of a donation to charity in return for granting interviews with medical representatives). The use of competitions, quizzes and suchlike, and the giving of prizes, are unacceptable methods of promotion.

Section 303 of the Regulations sets out offences for both the person who gives and the person who solicits or accepts any gift. In addition, the Bribery Act 2010 applies: in addition to the ongoing corporate liability for employees engaged in bribery, companies that fail to put in place adequate systems for avoiding conduct by its employees and associated persons amounting to bribery may also be guilty of an offence.

Closely interlinked with the Bribery Act, the Procurement Directive 2004/18/EC provides for a sanction of debarment from public procurement to any candidate who has been convicted of an offence, of which the contracting authority is aware. While Member States were able to include a derogation in national legislation (allowing for the right to override this exclusion where it was in the general interest), there is no such derogation in the UK. The UK government has indicated that debarment from public procurement is discretionary where a company is convicted of failing to prevent bribery by an associated person. However, debarment is mandatory if a company is convicted of active bribery, including bribery of a foreign public official.

In addition, the National Health Service (NHS) has published general Guidelines on Commercial Sponsorship, setting out ethical standards that all health professionals must observe. For example, NHS staff and contractors must refuse to accept gifts, benefits, hospitality or sponsorship of any kind that might reasonably be seen to compromise their personal judgment 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 provision of medical and educational goods and services (MEGS) in the form of donations, grants and benefits in kind to institutions, organisations or associations that are comprised of health professionals and/or that provide healthcare or conduct research are only allowed where: the gift complies with the rules on MEGS for healthcare professionals (see question 4.4) or are made for the purpose of supporting research; they are documented and kept on record by the company; and they do not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

In addition, the Department of Health encourages "joint working" between the NHS and the pharmaceutical industry (e.g. through interaction with those responsible for delivering and administering healthcare) in ways compatible with the ABPI Code. Clause 18.5 of the ABPI Code addresses joint working in some detail. An executive summary of a joint working agreement must be made public in relation to joint working projects started on or after 1 May 2011 or ongoing on that date.

4.4 Is it possible to provide medical or educational goods and services to doctors that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for or an increased market share for the products of the provider of the goods or services?

MEGS can be provided where the gift or donation is intended to enhance patient care or to benefit the NHS and maintain patient care (Clause 18.4 of the ABPI Code). However, such a gift or donation must not be offered as an inducement to an individual prescriber or group of prescribers to prescribe or use any particular medicine. Items donated may bear the company name, but cannot bear a product name.

The ABPI Code also contains detailed guidelines on the provision of MEGS to the NHS. For example, the recipient of any services must be provided with a written protocol setting out the details of the arrangement and, while a company may sponsor a nurse, the nurse must not be used to promote the company's products. In addition, companies are recommended to inform relevant parties (e.g. NHS Trusts, primary care organisations) of their activities, particularly where the provision of MEGS would have budgetary implications for the parties involved.

The free provision of MEGS to doctors (or other persons qualified to prescribe or supply relevant medicinal products), which provide

a personal benefit to them, constitutes an inducement to prescribe. The provision of MEGS must, therefore, be kept entirely separate from promotional activities, and this principle should be reinforced in the training of sales representatives. Prescribers must not, for example, be selected as potential recipients of an offer of MEGS on the basis of their prescribing habits.

Where MEGS improve awareness of a particular disease or assist in diagnosis, this may expand the overall market for relevant treatments without promoting any particular medicine. The ABPI Code confirms that such market extension activities will be acceptable if conducted in accordance with the ABPI Code. However, if the provision of such services leads, or appears to lead, to a change in prescribing habits, there is a risk that the PMCPA will draw an adverse conclusion about the company's and the prescriber's motives, in the absence of clear evidence to the contrary.

4.5 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 ABPI 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 what arrangements would qualify, although the MHRA Blue Guide states: "these are primarily financial terms and normally cover cash discounts or equivalent business discount schemes on purchases of medicinal products, including volume discounts and similar offers such as "14 for the price of 12", provided they are clearly identified and invoiced".

In the case of over-the-counter medicines, while multiple purchase promotions for consumers are not illegal, the MHRA strongly discourages offers related to analgesics, because of the risk of overdose.

4.6 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.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

The 2009 Pharmaceutical Price Regulation Scheme describes patient access schemes as schemes proposed by a pharmaceutical company and agreed with the Department of Health (with input from the National Institute for Health and Care Excellence) in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines.

While such arrangements are uncommon, a number of such schemes have been introduced. The ABPI Code confirms that patient access schemes are acceptable in principle, but they must be carried out in conformity with the Code.

Patient access schemes are categorised as: (i) financially-based schemes (discounts or rebates are offered depending on the number of patients treated, the response of patients treated or the number of doses required); or (ii) outcome-based schemes (where the price of the product may be increased or a rebate paid in light of additional evidence collection, or formal risk-sharing schemes where price adjustments will be made based on outcomes obtained relative to those anticipated in the terms of the scheme).

4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

Companies may sponsor Continuing Medical Education (CME) programmes for health professionals, but any such support must be non-promotional and must comply with the rules of the appropriate Royal College responsible. An application should be made to the relevant Royal College for accreditation of a meeting as CME.

The fact that a meeting or course is approved for CME does not mean that the arrangements are automatically acceptable under the ABPI Code, and company involvement must be reviewed to ensure that it complies with the Code, particularly in relation to hospitality. A company may provide proposals to CME organisers for programme content, speaker and venue selection. In addition, subject to obtaining the agreement of the event organiser, a company may make available information about its products. A company may pay registration fees for health professionals to attend a CME event and, subject to the restrictions outlined in section 5 below, may also provide travel and subsistence expenses associated with attendance. Health professionals may not, however, be paid an honorarium merely for attendance. There is generally no bar to the presence of sales representatives at a CME event.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?

This is governed by section 300 of the Regulations (reflected in Clause 19 of the ABPI Code): hospitality at either a meeting for the purpose of promoting a medicinal product or at an event held for purely professional or scientific purposes, must be strictly limited to the main purpose of the event and must only be provided to healthcare professionals. Hospitality includes sponsorship of attendance at the meeting or event, and the payment of travel or accommodation expenses.

The ABPI 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 to UK health professionals, whether the meeting takes place in the UK or 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?

Clause 19 of the ABPI Code allows the payment of reasonable travel costs, accommodation and enrolment fees by a company to enable a delegate to attend a scientific meeting, although the payment of such expenses in relation to persons accompanying the delegate is not permitted. Companies should only offer or provide economy air travel to delegates, although delegates may organise

and pay for the genuine difference between economy travel and business class or first class. The payment of compensation to healthcare professionals simply for attending a meeting is not permitted, although if a delegate is also a speaker, a reasonable honorarium may be paid.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of and the hospitality arrangements for scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual doctors to attend?

Where a company has sponsored a meeting, it is responsible for ensuring that all the arrangements (meeting content and hospitality) comply with the ABPI Code.

Where a company sponsors an individual doctor to attend a meeting organised by a third party, the company will be responsible for ensuring that the level of sponsorship is consistent with the ABPI Code. A pharmaceutical company is not, in principle, responsible for the contents of a meeting organised by an independent third party if the company has had no involvement or influence over such content and can demonstrate that this is the case.

5.4 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 arrangements must relate to genuine consultancy or other services and a written contract should be agreed before the services commence. The number of doctors involved in such activities must be limited, and there should be objective reasons for including the doctor, linked to his interest or expertise. Clause 20 of the ABPI Code obliges companies to include provisions in contracts with consultants, requiring the consultant to declare the consultancy when writing or speaking about matters relating to the agreement or the company. Pharmaceutical companies must make publicly available details of the fees paid to consultants in the UK. The information that must be disclosed is the total amount paid in a calendar year to all of the consultants who have provided services; the total number of consultants must be given, but the names of the consultants need not be disclosed.

5.5 Is it possible to pay doctors to take part in post marketing surveillance studies? What rules govern such studies?

A pharmaceutical company may pay compensation to doctors or institutions conducting non-interventional post-marketing experience or surveillance programmes. Clause 13 of the ABPI Code provides that all prospective studies that involve the collection of patient data must have a genuine scientific purpose and must not be used as a mechanism for promoting the company's products. Each study must be conducted pursuant to a protocol and be the subject of a contract between the health professional and/or the institute at which the study takes place, and the pharmaceutical company. Ethics committee and regulatory authority approvals may be required.

Institutions and investigators must be selected based on their experience or ability to meet the enrolment requirements, and must adhere to the principles of good clinical practice. A health professional's or institution's history of, or potential for, purchasing or prescribing company products may not be taken into account in the selection. Compensation may be paid on a per patient basis, but must be reasonable and commensurate with the services performed. An investigator should not be compensated for performing a medical evaluation that he would have performed regardless of his patient's participation in the clinical trial.

5.6 Is it possible to pay doctors to take part in market research involving promotional materials?

It is acceptable to enter into agreements with health professionals for *bona fide* consulting services, including market research activities, but such activities may not be used as a platform for disguised promotion. The name of the company does not need to be revealed in market research material; it is sufficient to state that it is sponsored by a pharmaceutical company. Appropriate compensation may be paid to respondents for their time; however, inducements that could influence respondents' opinions or behaviour must not be offered. The limitations imposed by Clause 20 of the ABPI Code (see question 5.4) do not apply where market research is limited (e.g. one-off telephone interviews or mailings), as long as remuneration is minimal.

5.7 Is there a requirement in law and/or self-regulatory code for companies to make publicly available information about donations, grants, benefits in kind or any other support provided by them to health professionals, patient groups or other institutions? If so, what information should be disclosed, from what date and how?

Clause 18.6 of the ABPI Code requires that the provision of MEGS in the form of donations and grants to institutions, organisations or associations that are comprised of health professionals and/or that provide healthcare or conduct research, be made public.

All donations and grants made in each calendar year must be disclosed. Disclosure must be in the calendar year following that in which donations and grants were provided, and the information must be made public within three calendar months of the end of the company's financial year. Local operating companies must take reasonable steps to disclose donations and grants provided by their overseas affiliates, head offices in the UK or overseas and UK based European offices.

Companies are also encouraged, but not obliged, to make publicly available information about any benefits in kind provided that they are covered by Clause 18.6 of the ABPI Code.

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; Part 14 of the Regulations sets out certain conditions that must be complied with. The advertisement must encourage the rational use of the product by presenting it objectively and without exaggerating its properties, and the advertisement must not be misleading. In addition, the advertisement must not:

- State, or imply that a medical consultation or surgical operation is unnecessary.
- Offer to provide a diagnosis or suggest a treatment by post or by means of electronic communication.
- By a description or detailed representation of a case history, lead to erroneous self-diagnosis.

- Suggest that the effects of taking a medicinal product are guaranteed, are better than or equivalent to those of another identifiable treatment or medicinal product, or are not accompanied by any adverse reactions.
- Use in terms that are misleading or likely to cause alarm, pictorial representations of changes in the human body caused by disease or injury, or the action of the medicinal products on the human body.
- Refer in terms that are misleading or likely to cause alarm to claims of recovery.
- Suggest that the health of a person who is not suffering from any disease or injury could be enhanced by taking the medicinal product, or the health of a person could be affected by not taking the medicinal product.
- Suggest that a medicinal product is a food, cosmetic or other consumer product.
- Suggest that a medicinal product's safety or efficacy is due to the fact that it is natural.
- Refer to recommendations by scientists, healthcare professionals or celebrities.
- Be directed to children.

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 section 284 of the Regulations.

Non-promotional information regarding POMs may be made available to the public in response to a direct enquiry from an individual or journalist and in certain other circumstances. Such information must be 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.

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?

Disease awareness campaigns are permitted (Annex 7 to the Blue Guide, Clause 22 of the ABPI Code). 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. The provision of advice on personal medical matters to individual members of the public is not permitted.

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 of a promotional 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. Press releases must be certified as compliant with the ABPI Code before being issued.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

Companies may provide corporate advertising and financial information to UK businesses and the financial press to inform shareholders, the Stock Exchange, etc. (Clause 22 of the ABPI Code). This information should be drafted with the view of keeping shareholders and the like fully aware of developments that may be material to the UK share price. Business press releases and corporate brochures should identify the commercial importance of the information and should be factual and balanced.

The ABPI Code alerts companies to the fact that a non-promotional item can be used for a promotional purpose and therefore come within the scope of the ABPI Code. Corporate information should always be examined to ensure that it does not contravene the ABPI Code or the relevant statutory requirements, and is not subject to the certification requirements.

6.6 What, if any, rules apply to meetings with and funding of patient support groups, including any transparency requirement as regards the recording of donations and other support in corporate reports?

Clause 23 of the ABPI Code addresses relationships with patient organisations. Pharmaceutical companies may interact with patient organisations or user organisations to support their work. However, such involvement must be transparent and all arrangements must comply with the ABPI Code. The limitations on the hospitality to be provided to healthcare professionals (see section 5) are also applicable.

Each company must make publicly available, at national or European level, a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support, which must include a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the significance of the support. A list of organisations being given support, including the monetary value of the support, must be made publicly available by the end of the first quarter of 2013.

Companies working with patient organisations must have in place a written agreement setting out exactly what has been agreed, in relation to every significant activity or ongoing relationship. The written agreement should set out the activities agreed and the level of funding, and refer to the approval process for each party. Material relating to working with patient organisations must be certified in advance by two persons on behalf of the company (Clause 14.3 of the ABPI Code).

There are other codes and guidelines applicable to specific patient groups, such as the Long Term Medical Conditions Alliance guidelines. In addition, patient organisations are likely to be covered by the rules of the Charity Commission (the regulator and registrar for charities in England and Wales), as well as their own codes.

7 The Internet

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

The same rules apply to digital communications as to other forms of advertising. Promotional material directed to a UK audience via the Internet is, therefore, subject to the ABPI Code. However, as a matter of practice, enforcement remains an issue, as the regulators

are only able to enforce the requirements against entities with a presence in the jurisdiction. Clause 24 of the ABPI Code indicates action will be taken where the advertisement has been placed on the Internet by or with the authority of a UK company and makes reference to the availability or use of a product in the UK.

The MHRA Guidance states that the UK rules will apply to "material posted on UK websites and/or aimed at the UK audience". Where companies include links from their UK site to their websites serving other countries, this should be made clear to UK users - users should not need to access non-UK sites to obtain basic information about the company's products.

Since March 2011, individuals with a concern about advertising on company websites can also make a complaint to the Advertising Standards Authority, who has dealt with a number of cases relating to advertising of medicines, particularly botulinum toxin products and homeopathic medicines.

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?

The MHRA Guidance states that websites aimed at health professionals "should ideally be access restricted" and that the public should not be encouraged to access material that is not intended for them. The Supplementary Information to Clause 24.1 of the ABPI Code provides that unless access to promotional material about POMs is limited to health professionals and appropriate administrative staff, a pharmaceutical company website or a company sponsored website must provide information for the public, as well as promotional material aimed at health professionals, with the sections for each target audience clearly separated and the intended audience identified. The rationale behind this requirement is to avoid the public needing to access material for health professionals unless they choose to.

7.3 What rules apply to the content of independent websites that may be accessed by link from a company sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

Although Clause 24.6 of the ABPI Code states that sites linked via company sites are not necessarily covered by the ABPI Code, a company will be responsible for ensuring material on a site linked from its website complies with the ABPI Code and laws relating to the advertising and promotion of medicines. For example, referring health professionals or patients to a website giving information about an unlicensed indication may be viewed as promoting that unlicensed indication.

If an independent website provides a link to a company website, the company will only be responsible for any breach of the ABPI Code that might arise as a result of the linkage (e.g. linking a site accessible by the general public to a site for health professionals) if the link was established with its knowledge and consent.

7.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

Companies are encouraged to place on their website reference material that is intended to act as a library resource for members of the public giving information relating to POMs that have marketing authorisations. It is considered good practice to provide, as a minimum, regulatory information comprising the SmPC, the patient information leaflet (PIL) and the public assessment report (EPAR or UKPAR), where such a document exists. Reference information may include the registration studies used for marketing authorisation applications and variations and any other studies, published or not, including those referred to in the SmPC, PIL, EPAR or UKPAR or available on clinical trial databases. Reference information may also include material supplied for health technology assessments, medicines guides and information about diseases. Reference information must represent fairly the current body of evidence relating to a medicine and its benefit/risk profile.

8 Developments in Pharmaceutical Advertising

8.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

The most significant development in the last year has been the entry into force of the consolidated medicines legislation, the Human Medicines Regulations 2012. As a result, updated versions of the MHRA Blue Guide and the ABPI Code have also been published.

In addition, the MHRA set up an informal forum, under the umbrella of the Heads of Medicines Agencies, for those responsible for regulation of medicines advertising in each Member State to exchange information. This became operational in early 2012; information has been exchanged on a number of issues, including disease awareness campaigns, competitions and sales representatives.

8.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

The MHRA is considering comments regarding medicines advertising that were received during the review of the medicines legislation in 2012. These cover three areas: (i) the use of lay language in advertising and the content of the statutory information required for advertising to healthcare professionals – consultation expected in mid-2013; (ii) the benefits and burden imposed by vetting of advertising for new active substances – review expected in mid-2013; and (iii) the consideration of potential benefits of relaxing the ban on advertising to adolescents with certain conditions such as acne.

In addition, the European Commission is conducting a review of the shortcomings of statutory information about medicines and is due to publish a report in 2013. It is not yet clear whether this will have implications for information about medicines more widely or for advertising.

8.3 Are there any general practice or enforcement trends that have become apparent in the UK over the last year or so?

Over the last year, the number of complaints about advertising has reduced from the higher numbers of the last few years, returning to previous levels. As in previous years, a high proportion of complaints received were about advertising to the public of botulinum toxin products and other POMs by cosmetic clinics and other Internet providers such as online clinics and pharmacies. A large number of complaints originated from competitors.

All complaints were resolved through voluntary agreement with the companies concerned, without the need to resort to statutory procedures.

8.4 Has your national code been amended in order to implement the 2011 version of the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals and the 2011 EFPIA Code on relationships between the pharmaceutical industry and patient organisations 2011 and, if so, does the change go beyond the requirements of the EFPIA Codes or simply implement them without variation?

The 2012 ABPI Code implemented the changes to the 2011 EFPIA Code without significant variation. Clause 17.2 of the ABPI Code provides that no more than four samples of a particular new medicine may be provided to an individual health professional during the course of a year, or for no longer than two years after that health professional first requested samples of it (see question 4.1). 'New medicine' is defined in the Supplementary Information as a product for which a new marketing authorisation has been granted, either following the initial application or following an extension application for a new indication that includes new strengths and/or dosage forms.

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