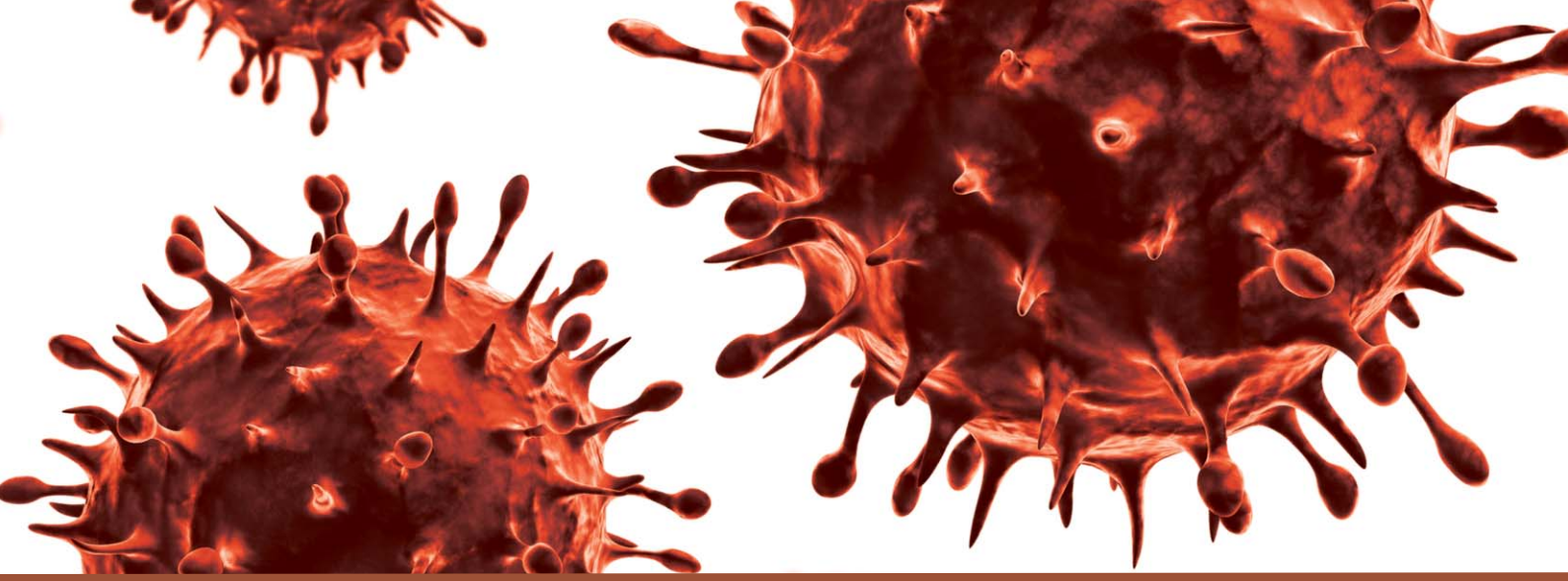

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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2014

11th Edition

A practical cross-border insight into pharmaceutical advertising

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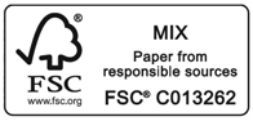

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Country Question and Answer Chapters:

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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 January 2014. 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, 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 including "anything designed to promote the prescription, supply, sale or use" of a medicinal product. This is stated to include: 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 of such inducements 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 state that the definition of "advertisement" does not include: packaging; correspondence answering specific questions about a medicinal product (which may be accompanied by material of a non-promotional nature); 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 relevant personnel involved in

promotion are appropriately trained on the requirements of 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 pharmacist registered in the UK. UK-registered dentists may also certify promotional material 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: (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 healthcare professionals of items to be passed on to patients; and (v) non-promotional material for patients or healthcare 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 (whether received from medical representatives or 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. Circumstances in which pre-use vetting may be required include: (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 vet initial advertising for all new active substances.

The duration of the vetting is commonly two 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.

It is also open to companies to seek guidance from the MHRA on proposed advertisements or to request a meeting to discuss issues that arise during the vetting procedure.

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. Where the MHRA 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. The findings of the Independent Panel have to be taken into consideration by the MHRA before a final decision on how the company promotes its product can be made. 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 proceeds to publish 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 issued under Section 306 of the Regulations by means of judicial review. In practice, this is unlikely to be successful unless the MHRA's procedure was demonstrably 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 provided 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.

The ABPI Code is administered by the PMCPA, and complaints made under the Code are considered by the PMCPA's Code of Practice Panel. The parties to a complaint have no right to appear before the Panel, but may appeal decisions made by it to the Code of Practice Appeal Board, which consists of representatives of industry and the medical professions, 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 sanctions, 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, 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 to the public as being the goods of another party, provided the party in question can show sufficient goodwill or reputation in the product and that such actions have caused damage to the claimant. A trade libel action may be brought by a trading corporation or company whose reputation is damaged.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to healthcare 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 variants not authorised)?

Section 279 of the Regulations prohibits the publication of advertisements for any medicinal product unless the product in question has a marketing authorisation, a traditional herbal registration, a homoeopathic medicinal product certificate of registration or an "Article 126a authorisation" (products authorised for justified 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 that neither the content nor the tone of the discussions appears designed to promote 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 also the approach taken by the MHRA Blue Guide.

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 healthcare professionals by the company? If so, must the healthcare 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 definition of "advertising" (which now appears in section 7 of the Regulations) was amended to exclude price lists. Accordingly licensed manufacturers and suppliers of unlicensed medicines are not prohibited from circulating price lists to healthcare professionals to whom the price of unlicensed products may be relevant (e.g. potential customers and budget managers). The ABPI Code clarifies that price lists relating to unlicensed medicines are not considered to be promotional provided that they include no product claims, and make it clear that the products are unlicensed. Such price lists can be sent to healthcare 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 advises on its website 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 on unauthorised medicines or indications 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 recognises that NHS organisations and others involved in the purchase of medicines need to estimate their likely budgets two to three years in advance, and therefore need information about the introduction of new medicines, or changes to existing medicines, which may significantly affect their level of expenditure. Accordingly, information may be provided in relation to products which contain a new active substance (or an existing active substance prepared in a new way) which have a significant new indication or a novel and innovative means of administration. The information must be directed only towards those responsible for budgets and not to prescribers; and it must be made clear whether the product has a UK marketing authorisation. The likely budget implications must be indicated and must be such that they will make a significant difference to NHS expenditure. The information must be limited to factual material, and should not be in the style of promotional material. The MHRA Blue Guide also recognises that such information may be provided "exceptionally".

2.7 Is it possible for companies to involve healthcare 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?

The ABPI Code states that, "market research is 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. The British Healthcare Business Intelligence Association (BHBIA) has also produced guidelines on market research entitled "The Legal and Ethical Framework for Healthcare Market Research".

On the basis of the ABPI Code and BHBIA guidelines, it is in principle acceptable to enter into agreements with healthcare professionals for *bona fide* consulting services, including market research activities. Market research exercises concerning launch materials for unauthorised products are permissible, provided they do not constitute a platform for disguised promotion to healthcare 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.

3 Advertisements to Healthcare Professionals

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

Section 294 and Schedule 30 of the Regulations state that, with the exception of abbreviated advertisements, all advertisements to healthcare professionals must contain essential information compatible with the SmPC and must contain the following:

- A marketing authorisation number.
- The name and address of the marketing authorisation holder (or that part of the holder's business that is responsible for the product's sale or supply).
- The classification of the medicinal product (i.e. POM, P or GSL).

- The name of the medicinal product.
- A list of the active ingredients, using their common names and placed immediately adjacent to the most prominent display of the name of the product.
- One or more of the product's indications for use, consistent with the terms of its marketing authorisation.
- A succinct statement of the entries in the product's SmPC relating to (i) adverse reactions, precautions and relevant contra-indications, (ii) dosage and method of use, and (iii) method of administration (where not obvious).
- The cost (excluding VAT) of the product.

Abbreviated advertisements are defined in section 295 as advertisements no larger than 420 square centimetres that appear in a publication sent or delivered wholly or mainly to persons qualified to present or supply medicinal products. They must contain essential information compatible with the SmPC and the majority of the information required for a full advertisement, but can refer to a website with information on adverse reactions, precautions, contra-indications and methods of use rather than including this information in the advertisement itself.

The general requirements in relation to advertisements do not apply to advertisements intended to be solely a reminder of the product, and that consist 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.

These rules 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 of the information contained in an advertisement need 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 publication of advertisements that refer to recommendations by scientists, healthcare professionals, or persons who because of their celebrity could encourage the use of the medicinal products.

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 stated 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 in order to ensure readers are not misled.

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?

Clause 7 of the ABPI Code provides that any comparison made between products must be accurate, fair, balanced, objective, unambiguous, based on an up-to-date evaluation of all the evidence and reflect the evidence clearly. Moreover, comparisons are only permitted in promotional material provided that: they are not misleading; they compare medicines advertised for the same needs or intended for the same purposes; no confusion is created between the medicine advertised and that of a competitor; there is no discreditation or denigration of a competitor's name or trade marks; no unfair advantage is taken of the competitor's name or trade marks; and the products are not presented as imitations or replicas of a competitor's products. 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 healthcare professionals?

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, the provision of such materials 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 (Supplementary Information to Clause 10.1 of 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 healthcare professionals with samples of products? If so, what restrictions apply?

Under section 298 of the Regulations, free samples are permitted, provided certain conditions are met. In particular, samples must only be provided to persons qualified to prescribe medicinal products in order for them to acquire experience in dealing with the product. Samples must not be provided to administrative staff.

Samples must be supplied on an exceptional basis only, and in response to a written, signed and dated request from the receiving healthcare professional. The Regulations require that a "limited number" of samples be provided – the ABPI Code clarifies that this means no more than four samples of a new medicinal product may be supplied in any one year to any one recipient.

Samples must be no larger than the smallest presentation available for sale, the supplier must maintain an adequate system of control and accountability, and no samples of controlled products may be supplied.

The ABPI Code imposes further restraints in relation to samples, including:

- Samples of a new medicinal product may be provided for no longer than two years after the healthcare professional first requests that sample (although this does not prohibit the provision of samples of new extensions of existing products).
- 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.
- Samples distributed by medical representatives must be handed directly to healthcare professionals, or a person authorised to receive them on their behalf.
- Samples must not be provided as an inducement to prescribe or supply any medicine, or for the sole purpose of treating patients.

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

Section 300 of the Regulations provides that no gift, pecuniary advantage or other benefit may be provided to healthcare professionals in connection with the promotion of medicinal products unless it is inexpensive and relevant to the practice of medicine or pharmacy.

The ABPI Code goes beyond the limitations established in the Regulations and prohibits nearly all promotional aids. This includes many of the traditional forms of promotional aids, such as coffee mugs, stationery, computer accessories, calendars, toys or puzzles for children, together with items relevant to the practice of medicine or pharmacy such as surgical gloves, tongue depressors or nail brushes (Supplementary Information to Clause 18.1). The only promotional items expressly permitted are inexpensive notebooks, pens and pencils for use by healthcare 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. The total cost to the donor company of all such items provided to an attendee must not exceed £6, excluding VAT.

Items intended to be passed to patients can be provided to healthcare 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 healthcare professional and the patient must be similar. They must directly benefit patient care.

Donations of money to healthcare professionals are not permitted, although donations to reputable charities in return for their attendance at meetings 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 is prohibited). The use of competitions, quizzes and suchlike, and the giving of prizes, are unacceptable methods of promotion.

Section 303 of the Regulations provides that any breach of the rules on the supply of free samples or the solicitation or acceptance of gifts, benefits or hospitality in breach of the Regulations is subject to a fine of up to £5,000 per offence. The Bribery Act 2010 also 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 amounting to bribery by their employees and associated persons 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 healthcare 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 healthcare organisations 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 healthcare 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. A formal written agreement must be in place for all working projects started on or after 1 May 2011 and an executive summary of the agreement must be made public before the arrangements are implemented.

4.4 Is it possible to provide medical or educational goods and services to healthcare professionals 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. MEGS may bear the company name, but must not bear the name of any medicine.

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 carried out in a manner compatible 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 – and closely monitors – 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 2014 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. 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 either simple discount schemes or complex schemes. Simple discount schemes are the preferred model because they place the least burden on the NHS and manufacturers. Complex schemes include all other types of PAS, such as arrangements involving rebates, stock supplied at zero cost, dose capping, and outcome-based schemes. Complex schemes are stated to be appropriate in exceptional circumstances only, and are unlikely to be suitable for a medicine widely used in primary care.

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

Companies may sponsor Continuing Medical Education (CME) programmes for healthcare professionals, but any such support must be non-promotional and must comply with the rules of the responsible medical royal college, faculty, specialist association or trade body. Most of the medical royal colleges and faculties have formal CME schemes, with accreditation and approval systems that consider the quality of proposed CME activities. 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 healthcare 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. Healthcare 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 healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

This is governed by section 300 of the Regulations, which states that hospitality at meetings or events, whether held for promotional or purely professional or scientific purposes, must be strictly limited to the main purpose or objective of the event, and must only be provided or offered to healthcare professionals. Hospitality is stated to include sponsorship of attendance at the meeting or event, and also the payment of travelling or accommodation expenses.

The Supplementary Information to Clause 19 of the ABPI Code states that administrative staff may be invited to meetings where appropriate but that spouses and other accompanying persons may not attend the meeting or receive any associated hospitality unless they are also healthcare professionals.

Clause 19.2 of the ABPI Code sets a threshold for the cost of a meal (including drinks) provided by way of subsistence at £75 per person, excluding VAT and gratuities. However, the Supplementary Information to Clause 19.2 states that the maximum of £75 is appropriate only in very exceptional circumstances, such as a dinner at a residential meeting for senior consultants or a dinner at a learned society conference with substantial educational content. The cost should normally be well below this figure.

The rules in relation to hospitality apply to any meeting attended by UK healthcare professionals, whether such meeting takes place in the UK or overseas.

5.2 Is it possible to pay for a healthcare professional 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 genuine registration 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 reasonable honoraria and reimbursement of out-of-pocket expenses may be paid to speakers, advisory board members and providers of other professional services.

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 healthcare professionals 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 healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?

It is possible to pay healthcare professionals and appropriate administrative staff to provide genuine consultancy or other services such as speaking at and chairing meetings, involvement in trials, studies and training, and participation in advisory board meetings or market research. However, Clause 20 of the ABPI Code states that a written contract should be agreed before the services commence and a legitimate need for the services must be identified in advance. The number of healthcare professionals involved in such activities must be limited to that necessary to achieve the identified need, and criteria for selecting the healthcare professionals should be directly related to that need. Hiring the healthcare professionals must not amount to an inducement to prescribe, and any compensation provided should reflect the fair market value of the service provided. The contracts with healthcare professionals should require them to declare these consultancy arrangements 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. From 2015 onwards the information that must be disclosed is the total amount paid in a calendar year to each consultant who has provided services. The names of the consultants must be disclosed, except in relation to payments for R&D work where disclosure should be on an aggregate basis.

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

A pharmaceutical company may pay compensation to healthcare professionals 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 be conducted for a scientific purpose

and must not be used as a mechanism for promoting the company's products. Each study must be conducted pursuant to a written protocol, and a written contract should be put in place between the healthcare professionals and/or the institutes at which the study takes place, and the pharmaceutical company sponsoring the study. Ethics committee 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 healthcare professional's or institution's history of, or potential for, purchasing or prescribing company products may not be taken into account in the selection. Remuneration may be paid on a per patient basis, but must be reasonable and reflect the fair market value of the work.

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

It is acceptable to enter into agreements with healthcare 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 the consultant is not consulted in a recurring manner, and that the remuneration is minimal.

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?

Pharmacy and general sale list medicines may be advertised to the general public, provided the advertisement encourages the rational use of the product by presenting it objectively and without exaggerating its properties, and is not misleading. Sections 280 to 293 of the Regulations set out additional restrictions on advertising aimed at the general public. In particular the advertisement must not:

- Lead to the use of a medicinal product for the purpose of inducing an abortion.
- Relate to medicinal products that contain narcotic or psychotropic substances.
- 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 and 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 that health of a person could be affected by not taking the medicinal product.
- Suggest that it is a food, cosmetic or other consumer product (and is not, therefore, a medicinal 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 principally at children.

An advertisement relating to a medicinal product must be presented in such a way that it is clear that it is an advertisement, and so that the product is clearly identified as a medicinal product. The advertisement must include the name of the medicinal product; the common name of the active ingredient; any information necessary for the correct use of the medicinal product; and a clear invitation to read the instructions carefully.

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?

Section 284 of the Regulations prohibits advertisements that are likely to lead to the use of POMs.

However, Clause 23.2 of the ABPI Code allows the provision of non-promotional information regarding POMs to the public in response to a direct enquiry from an individual and in certain other circumstances (including enquiries from journalists, dissemination of information via press conferences, press announcements, television and radio reports, public relations activities, etc.). Such information must be factual, balanced and must not be made for the purpose of encouraging members of the public to ask their doctors to prescribe a particular POM.

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 a 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 or 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 appropriate information on both their existing medicines and those not yet marketed to the UK business and financial press in line with their obligation to inform shareholders, the Stock Exchange etc., of developments that may be material to their UK share price. Business press releases and corporate brochures should identify the commercial importance of the information and should be factual and balanced.

Clause 14 of the ABPI Code requires companies to take account of 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 the funding of, patient organisations?

Clause 24 of the ABPI Code states that 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.

Companies working with patient organisations must have in place a written agreement setting out exactly what has been agreed, including funding, in relation to every significant activity or ongoing relationship. Where patient organisations are engaged to provide any type of services to companies, such services must be for the purpose of supporting healthcare or research, and the similar restrictions apply as in relation to the engagement of healthcare professionals to provide expert services (e.g. there must be a legitimate need for the services, compensation must be reasonable etc. – see question 5.5). No company may require that it be the sole funder of a particular group or programme. Material relating to working with patient organisations must be certified in advance by two persons on behalf of the company (see question 1.3).

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 constitutions.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, what information should be disclosed, and when and how?

Clause 13.1 of the ABPI Code requires companies to disclose details of clinical trials in accordance with the IFPMA/EFPIA/PhRMA/JPMA's Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature. These guidelines include a requirement that current and future trials are registered within 21 days of enrolling the first patient, and that results are published within one year of marketing authorisation or one year from completion for marketed products. Companies should include information as to where details of their clinical trials can be found on the home page of their website.

The ABPI has published a clinical trial disclosure toolkit with good practice guidelines, disclosure checklists and template standard operating procedures for pharmaceutical companies.

7.2 Has your national code been amended in order to implement the 2013 EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations and, if so, does the change go beyond the requirements of the EFPIA Disclosure Code or simply implement them without variation?

The 2014 version of the ABPI Code incorporates the requirements of the EFPIA Disclosure Code without any significant variation. The latest changes do not, however, provide final guidance on how disclosures will be made. In principle, disclosure will be on the company's website but, if a central platform for disclosure in the UK is established, the use of that platform is likely to be obligatory. A template which companies can use to comply with the disclosure obligations is available to download from the PMCPA's website. A consultation on further changes to the ABPI Code in relation to the proposed disclosure arrangements is expected in summer 2014, with further requirements about the method of disclosure to be included in the 2015 version of the ABPI Code.

7.3 If the EFPIA Disclosure Code has not been implemented in the UK, is there a requirement in law and/or self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what information should be disclosed, from what date and how?

Whilst the EFPIA Disclosure Code has been implemented in the UK, the disclosure requirements do not apply to transfers of value made in calendar years prior to 2015. Any transfers of value made in 2014, therefore, remain subject to the requirements of the 2012 edition of the ABPI Code. The 2012 version of the ABPI Code requires disclosure of:

- All donations and grants to institutions, organisations or associations that are comprised of healthcare professionals and/or that provide healthcare or conduct research.
- Details of sponsorship of UK healthcare professionals and appropriate administrative staff in relation to attendance at meetings organised by third parties. The information which must be disclosed is the total amount paid in a calendar year in respect of all recipients and the total number of recipients. The total number of attendances at meetings sponsored in the year must also be given.
- Details of the fees paid to consultants in the UK for services such as chairing and speaking at meetings, assistance with training and participation in advisory boards, etc., together with details of payments made to consultants in relation to market research and payments in respect of accommodation and travel. The information which 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.

In each case disclosure must be in the calendar year following that in which the payments were made and the information must be made public within three calendar months of the end of the company's financial year. The names of individual recipients and consultants need not be disclosed.

8 The Internet

8.1 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 which is provided on 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 25 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 or an affiliate of a UK company, and makes reference to the availability or use of a medicine in the UK.

The MHRA Blue Guide 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, such as package leaflets, summaries of product characteristics, public assessment reports and other non-promotional material.

The MHRA has developed specific guidance for consumer websites offering medicinal treatment services. This states that, as a general principle, online services such as online clinics or pharmacies may promote the service they provide. This includes providing information on relevant conditions and their management, and may include a balanced overview of the range of therapeutic options. However, any such material should not draw attention to specific POMs.

The MHRA operates a targeted approach to action on clinics and other services offering treatments involving botulinum toxin products and other POMs. It focuses on clinic websites, and aims to ensure that customers seeking general information about a clinic or potential treatments are not presented with advertising for POMs. Where breaches of the advertising rules present risks to public health and safety, the MHRA's Enforcement Group takes robust action, and in 2013 it closed down over 1200 websites advertising and/or selling counterfeit and unlicensed medicines.

Individuals with concerns about advertising on websites can also complain to the Advertising Standards Authority, which has dealt with a number of cases relating to advertising of medicines, particularly botulinum toxin products and homeopathic medicines.

8.2 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 healthcare professionals?

The MHRA Blue Guide states that advertisements for POMs are acceptable only on websites whose nature and content are directed at healthcare professionals, and as such any sections of a website aimed at healthcare professionals should ideally be access restricted. If no restriction is applied, the sections for consumers and healthcare professionals should be clearly separated and clearly marked for the target audience. Open access websites should provide non-promotional information in public areas so that individuals do not need to access sections for healthcare professionals unless they choose to seek further detailed information. Actively directing members of the public to advertising material for POMs is likely to be contrary to the Regulations.

8.3 What rules apply to the content of independent websites that may be accessed by a 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 25.6 of the ABPI Code states that sites linked via company sites are not necessarily covered by the ABPI Code, PMCPA guidance on digital communications states that any website chosen by a company to link to from its website should stand up to scrutiny. Companies should be confident about the choice of linked sites and that these do not promote POMs to the public. For example, referring healthcare professionals or patients to a website giving information about an unlicensed indication may be viewed as promoting that unlicensed indication. It is preferable to link to the homepage.

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 healthcare professionals) if the link was established with its knowledge and consent.

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

The MHRA Blue Guide states that companies may include the following information in a website aimed at the public:

- Information on disease awareness and health education campaigns (see question 6.3).
- Patient information leaflets (PILs), summaries of product characteristics (SmPCs) and public assessment reports (PARs) for their POM products.
- Other non-promotional reference information about the product that fairly reflects the current body of evidence about the product and its benefit risk profile (such as the registration studies used for marketing authorisation applications and variations and any other published or unpublished studies including those referred to in the SmPC, PIL, PAR or available on clinical trial databases).

Where a company includes links from its UK site to parts of its website serving other countries, UK users should be made aware that they have chosen to access material aimed at users in other countries. UK users should not need to access non-UK parts of the website to obtain basic information about the company's products, and it is good practice for each page of the website to include a statement that makes clear the intended audience.

8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

In February 2014, the PMCPA published a revised Guide on Digital Communications. The Guide is an update to a previous version published in April 2011, and includes advice on how companies can

make the best use of digital communication tools such as Twitter, Facebook, Pinterest and Wikipedia whilst complying with the requirements of the ABPI Code. The Guide highlights that the use of social media to promote POMs is likely to be problematic, as it may not be possible to limit the audience to ensure that members of the public are not able to access the materials. Recent PMCPA cases have found that the dissemination of product information via Facebook and Twitter amounted to promotion.

9 Developments in Pharmaceutical Advertising

9.1 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 ongoing drive to improve transparency of the pharmaceutical industry's relationships with healthcare professionals, as reflected in the changes made to the 2014 ABPI Code in order to implement the EFPIA Disclosure Code. Whilst the declaration of payments to individually named healthcare professionals will not begin until 2016 in respect of payments made in 2015, in April 2014 companies started to publish aggregate details of payments made to healthcare professionals in 2013. The 2013 figures published by the ABPI indicated a slight reduction in the amounts paid over the same period in 2012 (from £40m to around £38.5m).

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

In February 2014 the MHRA launched a consultation on proposals for simplifying the information requirements for the advertising of medicinal products to healthcare professionals. The consultation is seeking input on various ways of increasing the number of cases in which advertisements can include pointers or links to detailed prescribing information, rather than the information being included in the advertisement. The options being considered are

- Extending the use of the abbreviated advertisement format to all general sale list (GSL) medicines.
- Extending the use of the abbreviated advertisement format to medicines that have been on retail sale through pharmacies for a minimum defined period.
- Allowing links to the full SmPC to be included in electronic advertisements, as an alternative to including prescribing information.

The changes will only affect advertising directed at healthcare professionals and other medicines retailers – no changes are proposed in relation to the requirements on advertising to the general public. Any changes would be achieved by way of an amendment to the Regulations, and the MHRA has stated that it envisages the amendments coming into force in October 2014.

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

The number of complaints received by the MHRA about advertising increased slightly in 2013 compared with 2012. As in previous years, a high proportion of complaints received were about advertising to the public of botulinum toxin products and other POMs. The MHRA has been increasing its focus on advertising for homeopathic products, and the 2013 increase was largely attributable to a group of complaints about the advertising of homeopathic products received from one campaigning organisation. The MHRA also saw an increase in the number of complaints about advertising on social media such as Facebook, and received its first Twitter complaints in 2013. Social media cases now account for more than 10% of the complaints received by the MHRA. All complaints were resolved through voluntary agreements with the companies concerned, without the need to resort to statutory procedures.

The MHRA resolved a total of 262 enforcement cases in 2013. These cases mainly concerned the advertising of POMs to the public, including clinics offering treatments for lines and wrinkles that made promotional references to botulinum toxin products, and online clinics and Internet pharmacies promoting POMs and unlicensed medicines for various medical conditions. The MHRA Enforcement Group closed down over 1200 illicit websites advertising and/or selling counterfeit and unlicensed medicines in 2013.

9.4 Has your national code been amended in order to implement the 2013 version of the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals (the EFPIA HCP Code) and, if so, does the change go beyond the new requirements of the EFPIA HCP Code or simply implement it without variation?

Many of the changes to the 2013 EFPIA Code were already covered by the 2012 ABPI Code. The other changes (such as the need to introduce a monetary limit on hospitality costs and the new wording regarding informational and educational materials, and items of medical utility) have been implemented in the 2014 ABPI Code without significant variation.

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Silvia Valverde is an associate in the firm's London office and a member of the food, drug and medical devices practice group. She has extensive experience advising life sciences companies on EU and UK regulatory matters covering a broad range of issues that arise throughout the life cycle of the product, including clinical research, licensing, supply and promotion.
Ms. Valverde also assists life sciences companies in developing and implementing global and regional compliance programmes, including conducting risk assessments, remediation plans, enhancing policies and SOPs, and training on the various aspects of compliance. Her experience as a secondee in both areas, regulatory and compliance, gives her a practical perspective when advising clients on complex regulatory and compliance issues. Ms. Valverde is used to working in liaison with legal, compliance and business teams in a large number of markets.
Ms. Valverde gained a Master's degree in European Community Law from the Universite Libre de Bruxelles (ULB) and trained at the European Medicines Agency (EMA) before qualifying as a UK solicitor in 2001. She is fluent in French, and is a native Spanish speaker.

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Ewan is an associate in the firm's London office. He is a member of the EU Life Sciences and Intellectual Property practices.
Ewan focuses primarily on the life sciences industry, with clients in the pharmaceutical, biotechnology and medical device sectors. His practice involves advising clients on regulatory issues relating to medical products and medical devices in the UK and at the EU level, including supply chain structuring, pricing and reimbursement, parallel imports, advertising and promotion, freedom of information and data protection.
Ewan also advises on drafting and negotiating a wide range of commercial agreements relating to the licensing, manufacture, distribution and sale of medical products and medical devices.
In addition to his work in private practice, Ewan spent six months on secondment to GlaxoSmithKline, where he advised on global manufacturing and supply chain issues.

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The team of 15 lawyers specialising in this field in London is complemented by Arnold & Porter's highly regarded pharmaceutical and medical devices regulatory practice headed by Dan Kracov in Washington, D.C., with a team of 20 lawyers.

For further information, please contact Ian Dodds-Smith in the London office on +44 20 7786 6100, or Dan Kracov in Washington, D.C. on +1 202 942 5120.

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