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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2017

14th Edition

A practical cross-border insight into pharmaceutical advertising

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General Chapter:

Country Question and Answer Chapters:

EDITORIAL

Welcome to the fourteenth edition of *The International Comparative Legal Guide to: Pharmaceutical Advertising*.

This guide provides the international practitioner and in-house counsel with a comprehensive worldwide legal analysis of the laws and regulations of pharmaceutical advertising.

It is divided into two main sections:

One general chapter. This chapter provides an overview of off-label use in the EU and U.S.

Country question and answer chapters. These provide a broad overview of common issues in pharmaceutical advertising laws and regulations in 29 jurisdictions.

All chapters are written by leading pharmaceutical lawyers and industry specialists and we are extremely grateful for their excellent contributions.

Special thanks are reserved for the contributing editor Ian Dodds-Smith of Arnold & Porter Kaye Scholer LLP, for his invaluable assistance.

Global Legal Group hopes that you find this guide practical and interesting.

The *International Comparative Legal Guide* series is also available online at www.iclg.com.

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PREFACE

It is a pleasure to have again been asked to provide the preface to *The International Comparative Legal Guide to: Pharmaceutical Advertising*, which is now in its fourteenth edition.

This year the guide contains one general chapter written by Arnold & Porter Kaye Scholer LLP and 29 individual chapters, the new ones of which are Russia, Singapore, Taiwan and Ukraine. The general chapter comprehensively covers the area of medicine off-label use in the EU and the U.S. Despite plenty of activity in the area, including a European Commission Report, the chapter suggests that little has been decided in either jurisdiction in this vexed area to provide certainty for manufacturers, and thereby patients, going forward.

As with other current editions in the ICLG series that I use as a reference point, this edition will be my first port of call when faced with thorny questions concerning pharmaceutical advertising.

Tom Spencer
Senior Counsel
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Chapter 8

England & Wales


Adela Williams


Silvia Valverde

Arnold & Porter Kaye Scholer LLP

1 General – Medicinal Products

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

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; mainly the Blue Guide – Advertising and Promotion of Medicines in the UK, September 2014 and general guidance published on the MHRA website.

In addition to control by the MHRA, most pharmaceutical companies operating in the UK agree to abide 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 2016. A new version is announced for 2018. 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. Companies who have not agreed to abide by the relevant Codes of Practice and the associated self-regulatory mechanisms are supervised directly by the MHRA.

In addition to the controls which specifically relate to medicines, in principle other general legislation may be relevant including, for example, 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). The MHRA works with the Advertising Standards Authority (ASA), the UK's independent regulator for general advertising across all media, and the Committee of Advertising Practice (CAP), the body responsible for writing and maintaining the UK Advertising Codes and providing authoritative advice on the rules, to maintain high and consistent standards.

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 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 uses the term "promotion", which is similar. Promotion under the ABPI Code therefore covers "any activity undertaken by a pharmaceutical company or with its authority which 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 a promotional 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 who supply POMs and have agreed to abide by the ABPI Code, should make sure that all relevant personnel involved in promotion are appropriately trained on Code requirements. 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 a person on behalf of the company. This person must be different from the person responsible for developing the material.

Materials that will be printed can be certified in electronic form by a company signatory in the usual way; however, such material must not be used until the company signatory has checked and signed the item in its final printed form (in those circumstances, the material will have two certificates and both must be preserved). The signatory 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.

All promotional materials must be certified, regardless of format (e.g. printed or electronic, audio and audio-visual). 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 (only the final documents need to be certified); (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. There is no need to certify or examine meetings which involve travel outside the UK if the only involvement is sponsoring a speaker to present at a meeting and the pharmaceutical company has not participated in the arrangements for the meeting in any way.

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 or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

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 establish high standards, and companies are expected to ensure that relevant staff are trained and validated 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. The ABPI Code provides that each company should have a senior employee who is responsible for ensuring that this document meets the requirements of the Code. There is an assumption that this responsible person is the managing director or chief executive or equivalent unless other formal arrangements have been made within the company. In addition, and in line with the requirements of Directive 2001/83/EC, the Regulations require marketing authorisation holders to establish a scientific service to compile and collate all information relating to the product. This legal requirement is mirrored by the ABPI Code.

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 any person concerned with the publication of advertisements relating to medicinal products 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. MHRA vetting does not guarantee compliance with the ABPI Code.

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). The PAGB reviews all of their members' advertising to the public against their code of practice.

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 Review Panel. The findings of the Review 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? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

Enforcement is by the Enforcement Group of the MHRA. In most cases, a person (including a company) who contravenes the legislation faces an unlimited fine. In addition (or alternatively), where individuals are involved in the publication or use of unlawful advertising, a period of up to two years' imprisonment may be imposed.

Prosecutions for advertising offences are extremely rare. A prosecution for illegal advertising relating to activities addressed to healthcare professionals has not occurred for many years. More recently, prosecutions have concerned products that are claimed to have medicinal properties, but that are not authorised as medicines, or 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 PCMPA's Code of Practice Panel. The parties to a complaint have no right to appear or be represented before the Panel, but may appeal decisions made by it to the Code of Practice Appeal Board, which includes 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 (£3,500 per matter for ABPI member companies, or £12,000 if the matter is unsuccessfully appealed). The Panel and/or Appeal Board also have the power in serious cases to require an audit of a company's promotional procedures or to refer the matter to the ABPI Board of Management, who may suspend or expel the company from the ABPI or direct that the company should no longer be included in the list of companies who have agreed to be subject to the ABPI Code of Practice (with the result that the company becomes subject to direct supervision by the MHRA).

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.

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 trademark law, passing off, trade libel or malicious falsehood. A trademark infringement action may be brought by the owner of the trademark 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 or (if malice can be demonstrated in relation to a statement) malicious falsehood 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".

The proactive provision of information by a pharmaceutical company about an unauthorised medicine or about the unauthorised use of a medicine is very likely to be seen as promotion in breach of the Regulations and the ABPI Code. There are certain exemptions, in certain circumstances, such as replies made in response to individual enquiries from members of health professions or other relevant decision makers, discussions at international meetings organised by learned societies, advance notification of new products to the NHS or the legitimate exchange of medical and scientific information during the development of a medicine. However, each one of these activities must be considered on a case-by-case basis as the context in which the exchange takes place and the audience will be important factors in determining whether the activity is acceptable.

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 and/or off-label information be published? If so, in what circumstances?

Information of genuine scientific interest that is not promotional may be published in relation to both unauthorised medicines and off-label use. If the publication has been sponsored by a pharmaceutical company, such sponsorship must be clearly indicated.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.

It is possible to issue press releases about unauthorised medicines and off-label use 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 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 your jurisdiction?

Following the decision in Case C-143/06 *Ludwigs*, the definition of "advertising" (which 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 other relevant decision makers 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 in its guidance on the supply of unlicensed medicinal products 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 in advance, and therefore require 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 has 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 or indications 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" (current version issued in September 2016).

On the basis of the ABPI Code and the 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 prescribe 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 trademark. 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 mentioned 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 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 publication of advertisements relating to a medicinal product 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 may be made?

Controlled 'head to head' clinical trial data are not required to support 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. Comparisons must relate to clinically relevant endpoints.

Where data from clinical trials are used as substantiation for any claims made, the trial must be registered and the results disclosed in accordance with regulatory guidelines (see below at question 7.1).

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 or indication which had not yet been authorised in your jurisdiction?

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 trademarks; no unfair advantage is taken of the competitor's name or trademarks; 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. Providing an unsolicited reprint of an article about a medicine constitutes promotion of that medicine and it should be accompanied by prescribing information (Supplementary Information to 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 (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?

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

4 Gifts and Financial Incentives

4.1 Is it possible to provide healthcare professionals with samples of medicinal 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 other relevant decision makers.

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 (non-monetary gifts made for a promotional purpose). These include many of the items distributed traditionally by companies, 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 aids expressly permitted are: inexpensive DVDs or memory sticks, etc. which bear educational or promotional material (which is compliant with the Code); and inexpensive notebooks, pens and pencils for use by healthcare professionals and other relevant decision makers attending scientific meetings, conferences and promotional meetings organised by the company. In the case of materials for use at scientific 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; however, if such items are included in conference bags provided at third party organised conferences, they should not include the company name or the name of any medicine or any information about medicines. The total cost to the donor company of all such items provided to an attendee must not exceed £6, excluding VAT. The perceived value to the recipient must be similar.

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 an unlimited fine and/or where an individual is found guilty of an offence, a period of up to two years' imprisonment. 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? If monetary limits apply, please specify.

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 they: comply with the rules on MEGS for healthcare professionals (see question 4.4, Clause 19 of the ABPI Code) 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.

Alternatively, the ABPI Code confirms that package deals, defined as commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits as part of the purchase price, are acceptable (supplementary information to Clause 18.1 of the Code). The Code specifically refers to apparatus for administration, the provision of training on its use or the services of a nurse to administer it as potential benefits which may be provided as a package deal. The transaction as a whole must be fair and reasonable and the associated benefits must be relevant to the medicine concerned.

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 20 of the ABPI Code addresses joint working in some detail. A formal written agreement must be in place for all working projects, 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 19 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?

While an offer of benefit contingent upon the purchase of medicinal products is not permitted, package deals (as described at question 4.3) are acceptable under the ABPI Code.

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 (PAS) as schemes proposed by a pharmaceutical company (a PPRS member 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 patient access scheme liaison unit (PASLU) within NICE works with manufacturers who are considering a patient access scheme for their medicine or treatment. The PASLU team looks at the proposal made by the manufacturer to see if it is a scheme that would work in the NHS, coordinates the evaluation of the proposal and produces guidance to the Department of Health. The ABPI Code confirms that PAS are acceptable in principle, but they must be carried out in conformity with the Code.

PAS 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 appropriate in exceptional circumstances only, and are unlikely to be suitable for a medicine widely used in primary care.

Commercial arrangements, similar to those categorised as PAS, may be negotiated directly with NHS England or with local NHS bodies and are not restricted to PPRS member companies.

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, including in relation to the hospitality provided. 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.

4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?

The Bribery Act 2010 which came into effect in July 2011 applies to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations.

The Act created two primary offences, bribing and receiving a bribe, and introduced two new offences of bribing a foreign public official and of failing to prevent bribery. The latter is of particular concern to pharmaceutical companies as it establishes a strict liability regime, under which companies may be liable unless they can show that they had adequate procedures in place to prevent the offending activity. This means that the pharmaceutical company's own code of ethics or compliance and its implementation have now the dual role of achieving compliance with the applicable laws and codes and contributing to its "adequate procedures" defence.

The Ministry of Justice and the Serious Fraud Office (SFO) have issued guidelines on what conduct would or would not be likely to be prosecuted. However, this guidance should be read with caution by the pharmaceutical industry as its activities are guarded by a different set of ethics than other industries dealing with less regulated products. For example, the Ministry of Justice guidance considers taking foreign clients to a football match with the purpose of cementing good relations as a permitted hospitality, whereas taking healthcare professionals to such events would constitute a breach of the GMC Good Medical Practice Code and the ABPI Code. Such activity would constitute improper performance of a relevant function and therefore a breach of the Act.

In addition, the territorial reach of the Act is extensive and applies beyond activities taking place in the UK. Pharmaceutical companies, wherever they are incorporated, may be liable for acts of bribery if such acts or omissions occur in the UK. If the same acts or omissions occur outside the UK, then the UK courts will have jurisdiction over companies incorporated in the UK.

There is a Memorandum of Understanding between the ABPI, the PMCPA and the SFO dealing with the overlap of responsibilities arising from the interactions between pharmaceutical companies, healthcare professionals and other stakeholders and in particular,

those activities covered by the ABPI Code and the Bribery Act. Although both bodies deal with complaints whatever their source, the SFO focus is on dealing with complaints that are not covered by the ABPI Code or other self-regulatory authorities and which meet its criteria of serious fraud.

An additional concern linked with the Bribery Act arises from the Procurement Directive 2004/18/EC, which 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.

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 and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? 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 22 of the ABPI Code states that other relevant decision makers 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 22.2 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 22.2 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. However, the maximum of £75 for meals and subsistence does not apply when a meeting is held outside the UK in a country where the national association is a member of EFPIA and therefore covered by EFPIA Codes. In such circumstances, the limits in the host country code of conduct will apply.

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 22 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. Further, if the flight is for more than six hours, premium economy flights are permitted. 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. Even where a company has provided funding to an independent third party organisation for purposes, including the holding of a meeting, but has no control over the arrangements for the meeting or its content, it would be prudent for the company to include requirements for Code compliance in its contract with the third party organisation.

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 sponsorship arrangements are consistent with the ABPI Code. A pharmaceutical company is not, in principle, responsible for the content of a meeting organised by an independent third party if the company has had no involvement in 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 other relevant decision makers 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 23 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 the specified purpose. Recruitment of healthcare professionals should 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, where consent is given, 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 23 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 26.2 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 26.2 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 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? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

Both options are 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 27 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 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 organisation, such as the National Voices and ABPI Working Together, Delivering for Patients 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.

6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

Companies may provide healthcare professionals with items intended to be passed on to patients provided they are part of a patient support programme, the details of which must be appropriately documented and certified in advance. Such items should cost no more than £6, excluding VAT, and the perceived value to the healthcare professional and the patient must be similar. Items must directly benefit patient care and may bear the name of the company providing them. They must not be given to administrative staff unless they are to be passed on to a healthcare professional. Although such items may not be given out from exhibition stands, they may be exhibited and demonstrated on stands and requests for them accepted for later delivery. Examples of items which might be acceptable are a peak flow meter as part of a scheme for patients to regularly record readings or a pedometer as part of a scheme to encourage exercise.

In limited circumstances items may be made available for the use of healthcare professionals even though they are not to be passed on to patients for them to keep, provided that the items have been appropriately documented and certified. This is where their purpose is to allow patients to gain experience in using their medicines whilst under the supervision of a healthcare professional. For example, an inhalation device (with no active ingredient) and devices intended to assist patients to learn how to self-inject.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

Prior to the implementation of the Clinical Trials Regulation 536/2014/EU which is currently due to come into operation in 2018, disclosure obligations in the UK are dealt with by the Medicines for Human Use (Clinical Trials) Regulations 2004/1031. These Regulations do not contain specific provisions on publication of clinical trial data. However, 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. In addition, companies must publish summary details and results of non-interventional studies in the same way as for clinical trials.

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

The PMCPA has found companies in breach of the ABPI Code where information and data from clinical trials have not been disclosed in accordance with the relevant requirements. One complaint led to 25 cases covering 35 products from 21 companies. Seven of the 25 cases were found to be in breach of the Code.

7.2 Is there a requirement in the legislation 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 companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?

The Regulations do not include a requirement for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations. In the UK, these requirements arise from the self-regulatory system, as described below.

7.3 Is there a requirement in your 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 companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

Clause 24 of the ABPI Code incorporates the requirements of the EFPIA Disclosure Code without any significant variation. Companies must document and publicly disclose certain transfers of value made directly or indirectly to healthcare professionals and healthcare organisations located in Europe. The transfers of value covered are: (i) joint working; (ii) donations, grants and benefits in kind provided to institutions, organisations and associations; (iii) contracts between companies and institutions, organisations and associations; (iv) sponsorship of attendance by healthcare professionals and other relevant decision makers at meetings; (v) fees and expenses paid to healthcare professionals and other relevant decision makers, or to their employers on their behalf; and (vi) contributions towards the costs of meetings paid to healthcare organisations or to third parties managing events on their behalf, which may include sponsorship of healthcare professionals by way of registration fees and accommodation and travel. The requirement to disclose transfers of value arises independently of whether the company has obtained a marketing authorisation for a medicinal product.

Disclosure of transfers of value to UK health professionals and health organisations by ABPI members and non-members who have agreed to comply with the Code and their affiliates, must be made on the central platform for disclosure in the UK. The use of the central platform is mandatory for ABPI members and non-members who have agreed to comply with the Code, but other companies may also use it Companies are free to provide additional disclosure by providing the information on their own company websites. A template which companies can use to comply with the disclosure obligations is available to download from the PMCPA's website.

The relevant information must be disclosed in respect of transfers of value made in 2015, and each calendar year thereafter; these disclosure requirements do not apply to transfers of value made in calendar years prior to 2015. Disclosure must be made annually, in the first six months after the end of the calendar year in which the transfers were made, and must remain in the public domain for at least three years from the time of disclosure.

Transfers of value to healthcare professionals can be aggregated on a category-by-category basis, but payments to healthcare organisations are required to be disclosed on a per activity basis. The term "healthcare professional" in relation to disclosure of transfers of value also includes any employee of a pharmaceutical company whose primary occupation is that of a practising healthcare professional.

Companies must publish a summary of the methodologies used to prepare the disclosure and identify each category of transfer of value to include a description of the recognition methodologies applied and the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues relating to the timing and amount of transfers of value.

7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

Prior to 6 May 2018, when the EU Data Protection Regulation will come into force, the position in the UK is governed by the Data Protection Act 1998. Under the 1998 Act, healthcare professionals retain the right to refuse to disclose their personal information and the right under the law to seek correction of mistakes or deletion of their information. If a healthcare professional, who has received transfers of value from a company, refuses to agree to the disclosure of one or more of such transfers of value the company will need to report such transfers on an aggregate basis. This will include situations where the healthcare professional declines to give consent or decides to withdraw consent under data protection legislation. The ABPI has confirmed that they cannot, and will not, mandate that their members only work with healthcare professionals who consent to disclosure. It is up to the companies to decide individually which healthcare professionals they will work with and the terms of those arrangements.

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 Regulations and the ABPI Code. However, the regulators are only able to enforce the requirements against entities with a presence in the jurisdiction. Clause 28 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 2015 closed down over 1,300 websites advertising and/or selling counterfeit and unlicensed medicines, 339 of which were domestic sites.

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 28.6 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 on 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 March 2016, the PMCPA published revised Guidance on Digital Communications. The Guide addresses cross-border privacy issues, as well as providing commentary on the use of email by pharmaceutical companies and revised 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 efforts made during the past two years to improve the transparency of the pharmaceutical industry's relationship with

healthcare professionals and other stakeholders, including through the move from aggregate disclosure to individual disclosure have resulted in the first tranche of data on transfers of value being published in July 2016. The data disclosed show that the pharmaceutical industry spends £340.3m on working in partnership with leading UK health experts and organisations to improve patient care. Despite a majority of healthcare professionals having expressed their support for the pharmaceutical industry drive for greater transparency, a lower than expected number of healthcare professionals disclosed payments from industry.

Closely linked to these efforts, in February 2017 the NHS issued a new guideline for NHS staff and organisations to manage conflicts of interest in the NHS. This was followed in March 2017 by the new Royal Pharmaceutical Society guide on Conflicts of Interest to support pharmacists identify and appropriately make declarations of interest.

With regards to other topics, the PMCPA updated in March 2016 its guidance on Clause 3 which deals with communications on unauthorised products. It also issued new guidance on certification, including certification of multi-company projects and new guidance on the provision of benefits in connection with the sale, purchase or promotion of medicines. The latter covers topics such as the offer of terms of trade, package deals, free goods and patient access schemes. In April 2016, the PMCPA issued detailed advice on the organisation of advisory boards. The Medicines Advertising Liaison Group composed of PMCPA, PAGB, ASA, CAP, Clearcase, Radiocentre and HFMA now includes advertising of devices.

In the international arena, the MHRA continues working with the ABPI and other self-regulatory bodies and through EFPIA and IFPMA.

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

The MHRA is currently consulting with various stakeholders about the requirements applicable to the provision of essential information in the context of product advertising, particularly with regards to POMs. A formal consultation about potential changes to the current legal requirements controlling the provision of essential information is expected for 2018.

With regards to self-regulation, the current ABPI Code, which was issued in January 2016 is expected to be updated and amended this year with a new version to be issued in 2018.

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

Following the trend of the past few years the level of complaints received by the MHRA in 2016 about medicines advertising has been stable and low. With 171 complaints received. None of the complaints triggered corrective statements.

As in previous years, a high proportion of the complaints received (90%) were about advertising to the public of botulinum toxin products and other POMs. The MHRA states in its annual report for 2016 that the advertising material that was the subject of these complaints predominantly appeared on websites, but the MHRA continues to see an increase in the number of complaints about advertising on social media such as Facebook and Twitter.

All complaint cases received by the MHRA in 2016 were concluded through voluntary agreement with the companies concerned, most cases being dealt under self-regulation, without the need to resort to statutory procedures.

Some large supermarkets and other retailers were found not to be adhering to the MHRA guidelines on OTC sales of aspirin and paracetamol. In particular the limits of no more than two packs in one transaction and the limits to promotional offers for such products had not been respected. The MHRA wrote to all retailers identified and met with the British Retail Consortium (BRC) to discuss the issues raised. BRC agreed to work with their members to ensure that they and their staff were aware of the legal and voluntary restrictions in place to protect vulnerable individuals. MHRA continues to monitor the safety of analgesics in use. Should there be evidence of a significant risk to public health, MHRA would consider whether further regulation was necessary.

Finally, the MHRA's Operation Pangea sized £13.6M of unlicensed and falsified medicines in 2016.

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Adela Williams is a partner in Arnold & Porter Kaye Scholer's London office. She is also medically qualified.

Her practice focuses on the regulation of medicinal products and medical devices in the UK and at EU level, particularly in relation to clinical trials, marketing authorisations and advertising, and promotional issues, including legal proceedings arising from the decisions of regulatory bodies. She is frequently asked to provide advice in relation to proceedings before the Prescription Medicines Code of Practice Authority and its Appeal Board arising from alleged breaches of the ABPI Code on promotion of medicines and related activities.

She provides advice to clients in relation to pricing and reimbursement issues. This area of her practice includes both statutory and voluntary pricing regimes (PPRS) in the UK and representation at hearings before the PPRS dispute resolution panel. She also advises clients in relation to all stages of health technology appraisals by the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Consortium, and the All Wales Medicines Strategy Group, and also in relation to assessments by the Cancer Drugs Fund. She frequently represents clients at NICE appeal hearings and has acted on behalf of the manufacturer company in two of the three applications for judicial review brought against NICE in the Administrative Court.

She has substantial experience representing pharmaceutical and medical device clients in product liability litigation (unitary actions and group litigation), including claims involving unlicensed medicines in the research context as well as marketed products. Such litigation has often involved co-ordinating proceedings within the EU and advising on forum and other jurisdictional issues.

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Silvia Valverde has extensive experience advising life sciences companies on EU and UK pharmaceutical legislation covering a broad range of issues, with a particular focus on advertising, interactions with healthcare professionals and other stakeholders, research, licensing and supply.

Silvia has also worked with a large number of life sciences clients on compliance maters assisting in internal investigations, and developing global and regional compliance programmes, risk assessments, remediation plans and training.

As the professional support lawyer of the EU Life Sciences practice of the firm, Silvia provides regular training and updates to the team and clients on the developments in pharmaceutical legislation and analyses legal and market changes contributing to the team's work and publications.

The combination of her pharma regulatory work and her secondments in house to multi-national pharmaceutical clients has given her a practical perspective when assisting on complex compliance issues and cross-border matters. Silvia is a dual qualified lawyer with an international background and is used to working with legal, regulatory, compliance and business teams in multiple markets.

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Arnold & Porter Kaye Scholer LLP is an international law firm known for its innovative thinking, and effective client advocacy in more than 30 areas of practice. The firm has approximately 1,000 lawyers working in 9 offices in the US, together with offices in London, Brussels, Frankfurt and Shanghai.

The EU life sciences team, headed by Ian Dodds-Smith and based in London, has unrivalled experience in advising on every aspect of the regulation of medicines, devices, cosmetics, foods and borderline products. The team includes a number of lawyers with scientific qualifications, including two physicians. It is regularly ranked as the leading firm providing regulatory advice and specialist litigation services to the life sciences sector.

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

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