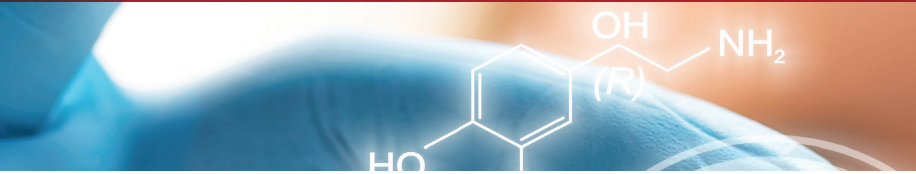


Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



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United Kingdom

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Introduction

The promotion of medicinal products in the United Kingdom is regulated by a combination of statute and government, industry and professional voluntary codes of conduct, together with professional rules and guidance introduced by the bodies regulating the prescribers themselves (healthcare professionals or HCPs).

The regulation is not always consistent, but the recurring themes running through the various sources are proportionality and relevance as regards promotional effort.

The ultimate goals are the protection of patients and upholding confidence in the healthcare industry, and the overriding principle is that pharmaceutical companies must not bring discredit upon or reduce confidence in the wider industry, for example, by promoting certain products directly to patients, on the one hand, or by using or being perceived to use inappropriate pressure or inducements to encourage doctors to prescribe their products, on the other.

The Regulatory Framework

A distinction is drawn in English law between medicinal products and medical devices. A “medicinal product” is “any substance or combination of substances presented as having properties of preventing or treating disease in human beings.”¹ This includes both proprietary and generic pharmaceuticals, and biologics and biosimilars. Conversely, a “medical device” is defined as “any instrument, apparatus, appliance, software, material or other article,” used for the purpose of “diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap” and includes devices “intended to administer a medicinal product or which incorporate as

¹ Human Medicines Regulations 2012, Regulation 2

an integral part a substance, which if used separately, would be a medicinal product.”²

The Human Medicines Regulations 2012³ (the “Human Medicines Regulations”), as amended, which implement European Community law⁴, impose restrictions and requirements that must be followed in all forms of advertising and promotion of medicinal products, and in the provision of free samples. The Human Medicines Regulations consolidate and replace the previous regimes contained in the Medicines Act 1968, the Medicines (Advertising) Regulations 1994 and the Medicines (Advertising Amendments) Regulations 2005.

By contrast, the Medical Devices Regulations 2002⁵ do not contain any provisions or restrictions on the advertising and promotion of medical devices.

The promotion of pharmaceutical products is also regulated by the legislation generally applicable to product promotion, including the Trade Descriptions Act 1968, the Consumer Protection from Unfair Trading Regulations 2008 and the Business Protection from Misleading Marketing Regulations 2008.

The Secretary of State for Health is responsible for ensuring compliance with the Human Medicines Regulations.⁶ This responsibility is devolved to the Medicines and Healthcare products Regulatory Agency (MHRA). In accordance with its regulatory role, the MHRA issues the Blue Guide which contains detailed guidance on

² Medical Devices Regulations 2002 (as amended by Medical Devices (Amendment) Regulations 2008/2936)

³ SI 2012/1916 (as amended by the Human Medicines (Amendment) Regulations 2015, Human Medicines (Amendment) (No 2) Regulations 2015, Human Medicines (Amendment) (No 3) Regulations 2015, Human Medicines (Amendment) Regulations 2014, Human Medicines (Amendment) Regulations 2013 and Human Medicines (Amendment) (No 2) Regulations 2013).

⁴ Directive 2001/83/EC (as amended by Directive 2004/27/EC).

⁵ SI 2002/618

⁶ Human Medicines Regulations 2012, Regulation 323



the advertising and promotion of medicines in the UK. The Guide is available on the MHRA website.⁷

The Human Medicines Regulations are supplemented by a number of voluntary standards applicable to the healthcare industry. With regard to prescription medicines, the Association of the British Pharmaceutical Industry (ABPI) has set guidelines that are embodied in the Code of Practice for the Pharmaceutical Industry United Kingdom (ABPI Code).⁸ The ABPI Code deals, amongst other things, with promotional activity relating to the prescription, supply, sale and administration of medicines. According to the ABPI, virtually all pharmaceutical companies operating in the UK have agreed to abide by the conditions of the ABPI Code, whether or not they are members of the ABPI. Companies must now appoint a senior employee to be responsible for ensuring that the company meets the requirements of the Code. There is an assumption that the responsible person will be the managing director or chief executive.⁹

With regard to over-the-counter (OTC) medicines, the Proprietary Association of Great Britain Codes of Practice for Advertising OTC Medicines (incorporating the Consumer Code and Professional Code) (PAGB Code) applies.¹⁰ The PAGB Code is very similar to the ABPI Code, detailing guidelines on general duties, acceptable information in advertising, hospitality and free goods and samples. Since OTC medicines may be promoted to both consumers and medical practitioners, the PAGB Code makes separate provision for each. As OTC medicines may be advertised to the public, the PAGB Code

⁷ www.mhra.gov.uk.

⁸ The current version is the 2009 Edition, as updated in November 2013, which can be downloaded from the PAGB website (www.pagbadvertisingcode.com).

⁹ The ABPI Code incorporates the principles set out in the EC Directive on the Community Code relating to medicinal products for human use (2001/83/EEC), as amended by Directive 2004/27/EC and the Codes and Criteria of several international and regional bodies, including the International Federation of Pharmaceutical Manufacturers and Associations, the World Health Organization and the European Federation of Pharmaceutical Industries' Associations. The version of the Code in force at the time of writing came into operation on 1 January 2015

¹⁰ ABPI Code, Clause 1.12 and Supplementary Information to Clause 1.12.

supplements the more general codes which govern advertising: the UK Code of Non-Broadcast Advertising, Sales Promotion and Direct Advertising (CAP Code) and the UK Code of Broadcast Advertising (BCAP Code), both of which are administered and breaches investigated by the Advertising Standards Agency.

Lastly, with regard to medical devices, the Association of British Healthcare Industries (ABHI) has set down the Association of British Healthcare Industries' Code of Business Conduct (ABHI Code of Conduct), which includes Guidelines on interactions with healthcare professionals (ABHI Interaction Guidelines) that are largely consistent with the ABPI Code. The ABHI also publishes the ABHI Guidelines on Advertisements & Promotions addressed solely or primarily to Healthcare Professionals (ABHI Advert Guidelines).

While membership of these industry bodies and compliance with the relevant codes of practice are generally voluntary, such industry codes are likely to be highly relevant to any assessment of whether a company had in place measures to prevent bribery, which is critical to the question of criminal liability under the Bribery Act 2010 (discussed further below).

In addition to the codes of practice detailed above, there are further codes and guidance that apply to prescribers and purchasers. For example, the General Medical Council (GMC) issues guidance to the doctors it regulates on how to conduct dealings with industry, and the General Pharmaceutical Council (GPC) has published and enforces standards of conduct, ethics and performance for pharmacists (the GPC Standards). Similarly, prescribers and those involved in procurement for the National Health Service (NHS) will be subject to specific internal rules and guidance on procurement and business ethics. For example, the Department of Health has published a guide entitled Commercial Sponsorship: Ethical Standards for the NHS (NHS Code). NHS Trusts publish their own codes of conduct on disclosures and transparency.



Permitted and Prohibited Practices

Gifts, Seminars, Hospitality and Entertainment

Regulation 300 of the Human Medicines Regulations provides that where medicinal products are being promoted to persons qualified to prescribe or supply such products, it is an offense to supply, offer or promise such persons any gifts, pecuniary advantage or benefit in kind, unless it is inexpensive and relevant to the practice of medicine or pharmacy.

Regulation 300 does permit the offering of hospitality (including the payment of travelling and accommodation expenses) to such persons at events for purely professional or scientific purposes, or at meetings or events for the promotion of medicinal products, provided such hospitality is strictly limited to the main scientific objective of the event and offered only to HCPs.

Lastly, Regulation 300 makes it an offense for any person qualified to prescribe or supply medicinal products to accept any gift, pecuniary advantage, benefit in kind, hospitality or sponsorship which is prohibited by Regulation 300.

In addition to the legal restrictions, the industry codes of practice described above seek to ensure that the promotion of medicines to HCPs and administrative staff (and also the public in the case of the PAGB Code) is carried out in a transparent, responsible, ethical and professional manner. This aim recognizes the reality of an environment in which seminars, and goods and services, are necessary for educational purposes, while professional independence and integrity are fundamental.

The ABPI, PAGB and ABHI Codes provide for a number of restrictions. All of these codes concur that interactions with HCPs, including gifts, benefits and transfer of value, should not be used to induce an HCP to use or recommend a company's products.

Under the PAGB Code, it is permissible to provide inexpensive gifts (costing no more than GBP6, excluding VAT) which are relevant to the recipient’s work; examples of acceptable gifts are set out, and include pens, notepads, diaries and calculators.¹¹ The PAGB Code also permits prizes up to GBP130 excluding VAT, and sets out some acceptable prizes, including relevant books and journal subscriptions, training courses, briefcases and electronic organizers, among others. However, the prizes must not be of the sort likely to be taken home, for example, microwave ovens.

Similarly, the ABHI Code permits inexpensive branded or non-branded gifts (but not cash or cash equivalents), which relate to the HCP’s practice, benefit patients or serve a genuine educational function.¹²

The approach under the ABPI Code is more strict, prohibiting the provision of all promotional aids, and allowing HCPs to be provided only with inexpensive notebooks, pens and pencils for use at scientific meetings and conferences. These items must not state the name of the medicine but may bear the name of the company providing them.¹³ It is not permissible to give any items for the personal benefit of HCPs or administrative staff.¹⁴ It is possible to provide “patient support items” which are inexpensive (under GBP6, excluding VAT), provided they are supplied to benefit patient care directly, and are part of a formal patient support program, the details of which have been appropriately documented and certified.¹⁵ The example given is of peak flow meters or pedometers to support wider campaigns around obesity.¹⁶

The provisions of the codes in connection with hospitality and meetings generally agree that, provided the hospitality offered is

¹¹ PAGB Code Rule 4.5.9.33.

¹² ABHI Interaction Guidelines – “Gifts”.

¹³ ABPI Code Clause 18.3.

¹⁴ ABPI Code Clause 18.1 (Commentary).

¹⁵ ABPI Code Clause 18.2.

¹⁶ ABPI Code Supplementary information to Clause 18.2.



reasonable in level and limited to the main purpose or scientific objective of the meeting or event, it is permissible to offer hospitality to HCPs.¹⁷ Any hospitality offered must be at a subsistence level only (including reasonable travel) and any hospitality of a social or sporting nature is not acceptable.¹⁸ A general theme across the codes is that sponsorship of meetings is permissible provided that the meetings have a clear educational content, focus on improving care and/or are aimed at medical advancement. The codes are also consistent in providing that for any meetings sponsored by pharmaceutical companies, the content of the meetings should be controlled. For example, the PAGB Code requires the fact of sponsorship to be disclosed in all of the papers relating to the meetings and in any published proceeding.¹⁹ The ABPI Code confirms that the declaration must be sufficiently prominent to ensure that readers are aware of it at the outset.²⁰ Where attendance of HCPs at a conference organized by a third party is sponsored by a company, that sponsorship must be declared in full, including details of all registration fees, costs of accommodation and any travel expenses.²¹ Where a meeting itself is sponsored by a company, all materials used in the meeting must be checked for compliance with the ABPI Code. Similarly, the ABHI Code provides that the sponsor of a meeting should have no input into the content of the meeting.²²

Note that meetings held at venues outside the UK may be permissible but there must be valid and cogent reasons for them to be held at the venue in question. For example, if most of the invitees are from outside the UK and, given their countries of origin, it makes greater logistical sense to hold the meeting outside the UK or, given the location of the relevant resource or expertise that is the object or

¹⁷ PAGB Code Rule 4.5.10.34; ABPI Code Clause 22.1; ABHI Interaction Guidelines – “Supporting Third-Party Educational Conferences”, “Member-Sponsored Product Training and Education” and “Sales and Promotional Meetings”.

¹⁸ ABPI Code Clause 22.1.

¹⁹ PAGB Code Rule 4.5.10.34.

²⁰ ABPI Code Clause 22.4.

²¹ ABPI Code Clause 22.5.

²² ABHI Interaction Guidelines “Conference Support”.

subject matter of the meeting, it makes greater logistical sense to hold the meeting outside the UK. Consideration should be given to the educational program, cost, venue facilities, nature of the audience and hospitality involved. In essence, the delegates must be attracted by the program, not the associated hospitality or venue.

Under Clause 1.7 of the ABPI Code, pharmaceutical companies must ensure they comply with all applicable codes, laws and regulations to which they are subject. This is particularly relevant when materials and activities involve more than one country or when a pharmaceutical company based in one country is involved in activities in another.

The ABPI Code recognizes that where “international” meetings are held in the UK, difficulties may arise with the promotion at such meetings of medicines not having a UK marketing authorization at the time. Provided certain specified conditions are met, such promotion is permitted.²³

Entertainment is permitted, but the same restrictions apply as to hospitality. Company-sponsored events are seen as designed for the promotion of the company’s products and as such are only acceptable if such hospitality is reasonable and subordinate to the main purpose of the event, which must be medical or scientific and offered to HCPs only. Thus, a half-hour presentation on a product, followed by a skiing trip or a meal in an expensive restaurant, for instance, would be unacceptable under the ABPI Code.

Other Promotional Activities

There are a number of limits imposed by the Human Medicines Regulations on promoting medicinal products. Among a number of restrictions on advertising, the Human Medicines Regulations include offenses for advertising unlicensed medicinal products²⁴ and for

²³ ABPI Code Clause 3.

²⁴ Human Medicines Regulations 2012, Regulations 279, 303.



issuing an advertisement to the general public that is likely to lead to the use of prescription-only medicines.²⁵

Medicinal products, including those that are prescription only, may be promoted to medical practitioners subject to certain limits imposed by the Human Medicines Regulations. Regulation 7 of the Human Medicines Regulations defines “advertisement” widely as including anything designed to promote the prescription, supply, sale or use of that product including, but not limited to, door-to-door canvassing, visits by medical sales representatives to persons qualified to prescribe or supply medicinal products, and the supply of samples.²⁶ A person may, as part of the promotion of a medicinal product, send or deliver any written material to a person qualified to prescribe or supply medicinal products, subject to the conditions specified in Regulation 297. An advertisement may be made only if a data sheet relating to the medicinal products in question is delivered with the advertisement or representation, and such advertisement or representation is not inconsistent with the particulars contained in the data sheet. The information contained in the data sheet should be presented clearly and legibly and be positioned for ease of reference. It is not acceptable for the information to be presented in such a way that the reader has to turn the material around to read the text, for example, diagonally or around the borders of a page.²⁷

The Human Medicines Regulations prohibit false or misleading advertisements. In particular, it is an offense (which may be punishable by an unlimited fine and/or imprisonment for up to two years) to: publish an advertisement for a medicinal product that is misleading; to publish an advertisement relating to a medicinal product that refers to claims of recovery in terms that are misleading or likely to cause alarm; or include in any advertisement a recommendation by a scientist or HCP.²⁸

²⁵ Human Medicines Regulations 2012, Regulations 284, 303.

²⁶ Human Medicines Regulations 2012, Regulation 7

²⁷ Human Medicines Regulations 2012, Regulation 294

²⁸ Human Medicines Regulations 2012, Regulations 280, 287, 289 & 303.

The Human Medicines Regulations prohibit certain activities when advertising to the public, which is relevant for OTC medicines. By way of example, the limits include not targeting advertisements directly, exclusively or principally at children,²⁹ not including medical or celebrity endorsements that may encourage consumption of medicinal products,³⁰ and not presenting the medicinal product as a foodstuff or cosmetic.³¹

For OTC medicines, it is a condition of membership in PAGB that all advertisements are submitted to PAGB for approval before they are released into the public domain.

In addition to the legal obligations detailed above, it is a requirement of the ABPI Code that promotional materials and activities are not disguised.³² Specific examples of activities not to be used as disguised promotion are market research, post-marketing surveillance studies, clinical assessments and similar activities.³³ This said, promotional material should in any event only be sent or distributed to those categories of persons whose need for, or interest in, the particular information can reasonably be assumed.³⁴

Importantly, while any joint working between HCPs and commercial organizations is permitted in accordance with the code, care must be taken to ensure that such working does not constitute disguised promotional activity but is carried out in a transparent and open manner. The ABPI Code has specific rules on joint working with health providers, setting out requirements to ensure it is done appropriately, for example, the joint work must be in the best interests

²⁹ Human Medicines Regulations 2012, Regulation 290.

³⁰ Human Medicines Regulations 2012, Regulation 289.

³¹ Human Medicines Regulations 2012, Regulation 288.

³² ABPI Code Clause 12.1.

³³ ABPI Code Clause 12.2.

³⁴ ABPI Code Clause 11.1.



of the patient and any agreements between the parties must be clearly recorded in writing.³⁵

In the first six months following the launch of a new medicinal product, an HCP may be sent an initial mailing giving detailed information about its use, including, for example, the summary of product characteristics, the public assessment report, the package leaflet and the product monograph, and no more than three other mailings about the medicinal product. Furthermore, no more than eight mailings for a particular medicinal product may be sent to an HCP in a year.³⁶ Mailings concerned solely with safety issues are exempt from these restrictions.

It should be noted that all the provisions and considerations mentioned above still apply where a pharmaceutical company is promoting its image only, and not a specific product. Such activity could still be an inducement to prefer that company, and hence its products.

In addition, all materials relating to medicines and their uses, whether or not promotional in nature, but which are sponsored by a pharmaceutical company, must clearly indicate the sponsorship. Even where companies are involved in the distribution of reports on meetings, such reports may constitute promotional material, and thus be fully subject to the ABPI Code.

An important requirement of the ABPI Code is that all promotional material, other than promotional aids, must include prominent information about adverse event reporting mechanisms. This could be satisfied by the inclusion of a statement such as “Information about adverse event reporting can be found at www.yellowcard.gov.uk “ and “Adverse events should also be reported to [the relevant pharmaceutical company].”³⁷

³⁵ ABPI Code Clause 20.

³⁶ ABPI Code supplementary information to Clause 11.2.

³⁷ ABPI Code, Clause 4.10 and Supplementary Information to Clause 4.10.

The PAGB Code is largely similar to the ABPI Code in this respect, although there are certain differences. For example, there is no requirement to include information on adverse event reporting under the PAGB Code (although it is stated that it may be helpful).³⁸ The provisions of the PAGB are generally more focused on the content of advertisements directed to consumers. The PAGB Code, therefore, reflects and provides further information on elements of the Human Medicines Regulations such as those relating to advertising to children and to celebrity or medical endorsements.³⁹

The ABHI Advert Guidelines apply to promotion aimed at HCPs. Advertisements aimed at the public are covered by the general law on advertisements. The ABHI Advert Guidelines have similar provisions to the other Codes, and require that advertisements be immediately recognizable as such and the commercial intent should be made clear,⁴⁰ as well as requirements of balance, fairness and lack of ambiguity.⁴¹

Samples

Samples (i.e., a small supply of a medicinal product) may be provided to members of the healthcare profession in order that they may familiarize themselves with it and acquire experience in dealing with it. The definition does not include titration packs, free goods, bonus stock or starter packs.

The Human Medicines Regulations apply to samples and specifically to labelling and packaging. In addition, the ABPI and PAGB Codes both include guidance on what constitutes a sample as well as how and to whom samples should be distributed. The provision of samples is not permitted under the PAGB Code.⁴²

³⁸ PAGB Code Clause 4.5.14.

³⁹ For example, see PAGB Code Clauses 3.5.8-3.5.10.

⁴⁰ ABHI Advertisement Guidelines Clause B.1.5.

⁴¹ ABHI Advertisement Guidelines Clause 2.1.

⁴² PAGB Code Clause 4.5.12.



The ABPI Code, however, permits samples, provided that no more than four samples per year of any one medicinal product are given to an individual HCP.⁴³ The HCP must be qualified to prescribe the product concerned. It is expressly forbidden to supply samples to administrative staff.⁴⁴

The ABHI Code expressly states that the section on gifts does not apply to providing appropriate samples for product evaluation. Provided the intention behind supplying the samples is not promotional, then the ABHI Code should not prevent this.

Consequences of Breach

While the ABPI, ABHI and PAGB Codes are voluntary, they are intended to be the primary means of regulating the sector, with the law providing a more general legislative framework. There is a complaints committee under each code to enforce the codes' provisions and consider any alleged breaches.⁴⁵

The MHRA, which is an agency of the Department of Health, is accountable to government ministers to consider breaches of the Human Medicines Regulations, including in relation to the promotion of medicines. The key function of the MHRA is to protect public health by promoting the safe use of medicines, ensuring that they are honestly promoted as to their benefits, uses and effects in compliance with current legislation. The MHRA in its guidelines encourages complainants to use the self-regulatory system (i.e., the various codes) in the first instance, as complaints can often be dealt with more easily in this way. As such, healthcare companies and HCPs should be mindful of the consequences, other than the purely legal, of ignoring the industry codes. Anyone, whether a consumer, a competitor

⁴³ ABPI Code Clause 17.2.

⁴⁴ ABPI Code Clause 17.1.

⁴⁵ The ABPI Code is administered by the Prescription Medicines Code of Practice Authority. The PAGB Code is administered by the PAGB Secretariat. Complaints under the ABHI Code go before an adjudication committee.

company or an HCP, is free to make a complaint about a member company under the codes, and they may do so anonymously.⁴⁶

If a breach of the relevant Code is found to have occurred, and the offending company has not already taken appropriate corrective action, the company will be asked to comply and the decision will be published. In more serious cases, the result can be advertised in the medical and pharmaceutical press or a public reprimand issued, and material can be recovered from those to whom it has been given. Furthermore, an audit of the company's procedures to comply with the Code can be carried out with the possible imposition of a requirement for the pre-vetting of all future material. In certain cases, companies may be expelled from the membership of the industry bodies.

A potentially more significant consideration arising from any breach of industry codes as they relate to interactions with HCPs may be their relevance to any allegations of bribery and, in particular, to any defense against a charge of the corporate offense of failing to prevent bribery, as discussed below.

A party found to be in violation of the Human Medicines Regulations could face an unlimited fine on summary conviction. On conviction on indictment, a party could face a fine, up to two years imprisonment or both.

If the company that is the subject of a complaint is not a member, the complaint may be reported to the trade association representing that company or, failing this, to the MHRA.

Professional Codes of Conduct

Paragraph 80 of the GMC Code of Good Medical Practice imposes an obligation on doctors that they “must not ask for or accept any

⁴⁶ If the company that is the subject of a complaint is not a member, the complaint may be reported to the trade association representing that company or, failing this, to the MHRA.



inducement, gift or hospitality which may affect or be seen to affect the way [they] prescribe for, treat or refer patients.”

The GPC Standards make similar provision for pharmacists, requiring that they “do not ask for or accept gifts, rewards or hospitality that may affect, or be seen to affect, [their] professional judgement”.⁴⁷

The guidance to the GMC Code of Good Medical Practice refers directly to the MHRA Blue Guide and the ABPI Code, for doctors to inform themselves of requirements in relation to the limits of acceptable behavior in relation to inducements, hospitality and other issues.

The NHS is a significant purchaser in the UK market, purchasing around 80 percent in value of all medicines used in the UK. The NHS Code directs NHS staff at all levels within the organization to refuse gifts, benefits, hospitality or sponsorship of any kind so as to ensure that they remain impartial. NHS staff must use local arrangements to declare publicly any commercial sponsorship (which is defined in the NHS Code as including any funding from an external source, including funding of all or part of the costs of a member of staff, NHS research, staff, training, pharmaceuticals, equipment, meeting rooms, costs associated with meetings, meals, gifts, hospitality, hotel and transport costs [including trips abroad], provision of free services [speakers], buildings or premises) linked to the supply of goods or services and be prepared to be held accountable for it. It is suggested that a simple ledger will suffice to avoid any unnecessary paperwork.

These arrangements do not apply to personal gifts of less than GBP25 per gift (e.g., gifts of Post-it pads, pens). However, gifts should be declared if several small gifts worth a total of over GBP100 are received from the same or closely related source over a 12-month period.

⁴⁷ GPC Standards para. 6.3.

The NHS Code provides that industry representatives organizing meetings are permitted to provide appropriate hospitality and/or meet any reasonable, actual costs that may have been incurred. If no hospitality is required, there is no obligation or right to provide any such hospitality, or indeed any benefit of equivalent value.

Liability Under Criminal (and Civil) Law

The Regulatory Framework

Criminal Law

The Bribery Act 2010 was introduced to overhaul the very complex legal framework on bribery and corruption that had developed over time. Existing offenses were clarified and new offenses were introduced.

The Act has extraterritorial effect, covering all activities by the company whether the bribery occurs within or outside the UK. Any company which carries on all or part of its business in the UK is caught by the Bribery Act. Companies may also incur liability for the actions of third parties who carry out business on behalf of the company, if the company receives a benefit from the provision of those services.

Civil Law

While the Bribery Act governs criminal liability for bribery and corruption, it should be noted that a company engaging in corrupt practices with employees of another may incur civil liability under express statutory provisions, with liability being imposed on both the individual as well as the organization involved in the corrupt conduct.



Permitted and Prohibited Practices

The Bribery Act sets out four offenses, namely: bribing,⁴⁸ being bribed,⁴⁹ bribing a foreign public official,⁵⁰ and a specific corporate offense of failing to prevent bribery.⁵¹

The definition of a bribe is very wide and includes the offer, promise or provision of any advantage (whether financial or not), where the offeror's intention is to induce the recipient to perform a function improperly or where the offeror knows that acceptance of the advantage is, in itself, an improper performance of the function.

This has the potential to capture many types of promotional expenditure, including, for example, corporate hospitality and sponsorship of practitioners. If the advantage given is lavish and disproportionate to common practice, there will be a greater inference that it was intended to induce improper behavior from the recipient.

In assessing whether the provision of any corporate hospitality to HCPs in the UK was improper, the normal practices of the relevant industry (including in this case the provisions of the ABPI Code, the ABHI Code and the PAGB Code) would be highly relevant. Similarly, since the industry codes are incorporated into the professional obligations of the HCPs, non-compliance by the HCPs would, in itself, be evidence of an improper performance of their functions, which may constitute bribery.

In relation to the bribery of foreign officials, the Bribery Act prohibits any financial or other advantage being offered, promised or given to a foreign official. To fall within the prohibition, the offeror's intention must be to obtain or retain business or a competitive advantage. Any local industry practices are irrelevant for the purposes of the Bribery

⁴⁸ Bribery Act 2010, Section 1.

⁴⁹ Bribery Act 2010, Section 2.

⁵⁰ Bribery Act 2010, Section 6.

⁵¹ Bribery Act 2010, Section 7.

Act, unless they are specifically permitted or required by local law.⁵² As such, even if it is commonplace in a certain country to make facilitation payments, the company making such payments would be in breach of the Bribery Act.

Under the previous regime, it was generally quite difficult to impose criminal liability on a corporate entity, as it was necessary to attribute the criminal intent to the guiding mind of the company. However, under the Bribery Act 2010, there is now an offense for commercial organizations that fail to prevent bribery by their employees and/or third-party representatives.

It is a defense to this corporate offense for a company to show that it had adequate procedures in place in order to prevent bribery.⁵³ In March 2011, guidance was issued by the Ministry of Justice setting out six principles around which the adequacy of procedures would be decided. These six principles are: proportionate procedures; top-level commitment; risk assessment; due diligence; communication; and monitoring and review. Again, industry practices such as those set out in the industry codes will be relevant to an assessment of whether procedures are proportionate, and full compliance with those codes is likely to help avoid a charge of bribery from being made out.

On a related note, it is important to note that NHS employees are employees and representatives of the state in the UK. Interactions with them may be relevant for other corruption legislation with extraterritorial effect, such as the US Foreign Corrupt Practices Act.

Sanctions

Criminal Law

Any individual found to have committed the offense of bribery, accepting a bribe or bribery of a foreign official is liable on summary conviction to imprisonment for a term not exceeding 12 months,

⁵² Bribery Act 2010, Section 5.

⁵³ Bribery Act 2010, Section 7(2).



and/or an unlimited fine; and on indictment, to imprisonment for a term not exceeding 10 years and/or to an unlimited fine.⁵⁴

Companies guilty of an offense, including failing to prevent bribery, may be subject to an unlimited amount.⁵⁵ Any senior officers with a close connection with the UK, who committed or consented to the commission of the offense, may also be prosecuted individually.

If a company is found guilty of an offense under the Bribery Act, that company may also be blacklisted from future government procurement activity.

Civil Law

Any contract which has been induced corruptly will be deemed illegal and, therefore, unenforceable pursuant to common law rules, which provide that a contract made for the purpose of committing a fraud on a third person or the public cannot be enforced and is deemed void from the outset.

Equitable principles allow the court to set aside a contract that has been entered into as a result of conduct, which is contrary to good conscience, which would include the procurement of a gift or other benefit by the exertion of undue influence.

A company that can show that its employee has been bribed may have claims against the company making the bribe for the dishonest assistance given to the employee in the conduct of his/her duties, and that company would be required to account for any profits made from entering into the arrangement.

⁵⁴ Bribery Act 2010, Sections 11.

⁵⁵ Bribery Act 2010, Sections 11(2) and 11(3).

Contracts with Healthcare Professionals and Medical Institutions

The formation and performance of all contracts between healthcare companies and HCPs or medical institutions will be governed by normal principles of English contract law, discussion of which is beyond the scope of this chapter. It is also not the purpose of this chapter to review the regulations and principles of good medical practice that may be applicable to clinical trials and other research-related contracts. However, any contractual relationship between a healthcare company and an HCP in the UK, the essential purpose of which is to promote the company and its products, will be subject to the same regulatory framework of statute and industry and professional codes that are described above.

The offering by a pharmaceutical company of contracts for the sponsorship or other financial support of an HCP is not a prohibited practice under pharmaceutical advertising law, the codes of conduct or the criminal (and civil) law. There is no requirement in the UK to obtain approval, nor any specific legal regime, but, as for all promotional activities, a sponsorship or other contract should not amount to an inducement. For example, if a healthcare company requires the sponsored HCP to purchase certain products, or the technique on which training is given is one in which only the company's products can be used (assuming it is not the only technique available for a particular treatment), this might be seen as an inducement for the purposes of the ABPI, ABHI and PAGB codes.⁵⁶

Although not directly applicable to the healthcare company that is seeking to sponsor an HCP or provide some other form of financial support, the impact of the professional codes of conduct on any contract should not be ignored.

⁵⁶ For the consequence of a breach of the ABPI, ABHI and PAGB Codes, please see above.



In view of the potentially serious consequences of a member of the healthcare profession failing to meet the applicable professional standards set by the GMC, while not a strict requirement, many HCPs may prefer interested healthcare companies to contract with the employing medical institution for purposes of sponsorship or other financial support (whether a grant for specific scientific research or otherwise), or at least to seek the institution's approval before contracting with the individual HCP. If a healthcare company does find itself contracting directly with the HCP, it would be advisable in any event to confirm that the terms of any employment or other contract between the HCP and a medical institution permit external contracts with independent pharmaceutical companies.

In any event, healthcare companies should aim to be as transparent as possible in all contractual dealings with HCPs and healthcare organizations. The industry codes may require publication of promotional material for HCPs, institutions or patient organizations. By way of example, the ABPI Code requires the company to have in place a self-certification system for confirming that such material complies with the ABPI Code (carried out by appropriately qualified and senior employees or officers of the company),⁵⁷ and requires that details of donations and sponsorship and of agreements with HCPs that may be construed as promotional, or executive summaries of such agreements be published on the company's website.⁵⁸

Transparency Obligations

Clause 24 of the ABPI Code contains specific transparency obligations in relation to "transfers of value" that pharmaceutical companies make to HCPs and healthcare organizations. "Transfer of value" is defined as a "direct or indirect transfer of value [made to an HCP or healthcare organization], whether in cash, in kind or

⁵⁷ ABPI Code Clause 14.

⁵⁸ For example, details of donations to institutions, organizations or associations comprised of HCPs, must be published, ABPI Code Clause 19.2 and executive summaries of joint working agreements between industry and healthcare institutions must also be published, ABPI Code Clause 20.

otherwise, whether for promotional purpose or otherwise, in connection with the development or sale of medicines.” Companies are required to document and publicly disclose the following such transfer of value:

- Joint working
- Donations, grants and benefits defined as medical or educational goods and services
- Contracts between companies and healthcare organizations
- Sponsorship of attendance by HCPs and other relevant decision makers at scientific or promotional meetings
- Fees and expenses paid to HCPs and other relevant decision makers when engaged as consultants
- Contributions toward the cost of meetings paid to healthcare organizations, or to third parties managing events on their behalf, which may include sponsorship of HCPs by way of registration fees and accommodation and travel

Disclosures must be made annually in respect of each calendar year. Disclosure must be in the first six months after the end of the calendar year in which the transfers of value were made (the first disclosures being required for any transfers of value made in 2015). The disclosures must remain in the public domain for three years, and companies must document all disclosures and retain the records for at least five years. Ideally, transfers of value should be disclosed in relation to each individual HCP recipient. However, where recipients of transfers of value cannot be identified for legal reasons, the amount attributable to such transfers must be disclosed on an aggregate basis. In addition, each company must publish a note summarizing the methodology used in preparing the disclosures.

Maintaining compliance with the transparency obligations of the ABPI Code can prove burdensome, particularly when preparing for



the first disclosures to be made in 2016. The project involves coordination of a company's finance, payments, compliance and legal teams. It is important that appropriate systems and processes are in place to ensure full compliance can be achieved.

Recommendations

In all promotional activities in the UK, pharmaceutical companies selling prescription-only medicines should be guided by the overriding principle, as enshrined in the ABPI Code, that such activities must not bring discredit upon or reduce confidence in the pharmaceutical industry. In dealing with HCPs, companies would be expected to observe the increasingly restrictive limits on their interactions, and there may be serious results from failing to do so, including potential allegations of bribery.

Companies selling OTC medicines and medical devices may be able to carry out more promotional activity under the details of their relevant rules (while always respecting the principle of not discrediting or undermining confidence in their industry), but should be aware that the tendency in all areas appears to be toward more restrictive regulation and should be monitored.

In all cases, companies selling medical products should have comprehensive policies in place for staff interacting with HCPs, which should be enforced effectively and on which full training should be provided. In this way, if an employee does behave inappropriately, the company will improve its chances of having a defense against charges of the corporate offense of failing to prevent bribery.

Where a company sells a mixture of OTC medicines, prescription medicines and/or medical devices, the risk of mistakes being made by employees as to the applicable rules will likely increase. In such circumstances, it would be advisable either to set one policy for all areas at the highest level (i.e., the ABPI Code) or, if practicable, to divide the business in such a way as to ensure representatives are only dealing with one type of product.

The following recommendations offer some guidance for best practice in the UK at the highest standard set by relevant regulations.

Do not make or offer gifts to individuals in the medical profession: Inexpensive stationery labelled with the company name (and not with any names of medical products) may be provided at meetings, but other than this, no items should be given for the personal benefit of HCPs.

Certain patient support items and promotional aids may be supplied for the benefit of patients, provided that these are also inexpensive and do not bear the name of any medical products (the name of the company is permitted).

If giving free samples, be sure to comply with Regulation 298 of the Human Medicines Regulations and industry codes of practice, particularly in terms of the recipients and the number and content of the samples.

When providing hospitality, consider whether it is:

- reasonable;
- strictly limited to the primary, medical or scientific purpose of the meeting or event; and
- offered only to HCPs.

When sending promotional material to HCPs, ensure that:

- the product is of a type that may be advertised (i.e., not an unlicensed product);
- the promotional material is not false or misleading and that any comments are verified; and
- a data sheet accompanies the promotional material, which complies with the requirements of the Human Medicines



Regulations and the industry codes, and the limits on how many times material may be sent, and to whom, set down in the industry codes are observed.

Further recommendations:

- Ensure any charitable donations made are modest and used for the practice of medicine.
- Volume rebates and discounts are acceptable, but they should not be dependent on purchases by certain individuals and should be part of normal commercial trade.
- Be transparent in all dealings with HCPs and medical institutions, and plan early to ensure compliance with transparency obligations. Put a steering committee in place to ensure proper processes and internal policies are developed. Utilize the technology of payment systems to reduce the burden of the process.

In conclusion, while the degree to which individual HCPs may be influenced by the promotion of healthcare products is uncertain, some forms of promotion are acceptable. Healthcare companies are advised to keep activities transparent, to properly record and account for all expenditures and, where possible, to deal with institutions rather than with individual HCPs on a personal level.



This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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