

PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES
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GENERAL
1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.
Medicines Specific laws and guidance: <ul style="list-style-type: none">• Part 14 of The Human Medicines Regulations 2012/1916 (HMR);• The Medicines (Advertising of Medicinal Products (No 2)) Regulations 1975/1326;• The Medicines (Labelling and Advertising to the Public) Regulations 1978;• The Cancer Act 1939 includes a ban on certain advertisements relating to cancer treatments;• The Medicines and Healthcare Products Regulatory Agency (MHRA) Blue Guide (the Blue Guide). Self-regulation: <ul style="list-style-type: none">• The Advertising Standards Authority (ASA);• The Broadcast Committee of Advertising Practice (BCAP);• UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (the CAP Code);• Code of Broadcast Advertising (the BCAP Code). Industry codes: <ul style="list-style-type: none">• The Association of the British Pharmaceutical Industry (ABPI) Code applies to prescription-only medicines. The enforcement body is the Prescription Medicines Code of Practice Authority (PMCPA).• The Proprietary Association of Great Britain (PAGB) for over-the-counter (OTC) medicines –<ul style="list-style-type: none">– the PAGB Consumer Code for Medicines (directed to consumers); and– the PAGB Professional Code for Medicines (directed to professionals). Medical devices <i>Laws</i> There are no laws specifically regulating the advertisement of medical devices in the UK. Nevertheless, medical devices might only be advertised within the terms of their authorisation. Self-regulatory codes: <ul style="list-style-type: none">• The Association of British HealthTech Industries Code of Ethical Business Practice, Part 3 (ABHI Code) – applies to advertising to healthcare professionals (HCPs), but not consumers, although the guidelines encourage those advertising to comply with their terms even for consumer advertising.• The Medical Devices Consumer Code is a self-regulatory code followed by members of the Proprietary Association of Great Britain (PAGB Code) (consumer advertising). General consumer advertising laws (medicines and medical devices): <ul style="list-style-type: none">• Non-broadcast advertising• Trade Descriptions Act 1968• The Business Protection from Misleading Marketing Regulations 2008• The Consumer Protection from Unfair Trading Regulations 2008 • Broadcast advertising• Broadcasting Acts 1990 and 1996• Communications Act 2003
2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?
Medicines The law defines advertising as 'anything designed to promote the prescription, supply, sale or use of a product' with the following considered to be advertising:

- door-to-door canvassing;
- visits by sales reps;
- supply of samples;
- inducements to prescribe or supply medicinal products;
- sponsorship of promotional meetings attended by those qualified to prescribe or supply medicinal products; and
- sponsorship of scientific congresses, including payment of travelling and accommodation expenses of persons qualified to prescribe or supply medicinal products.

The following are not considered an 'advertisement':

- a medicinal product's package or package leaflet;
- reference material and announcements of a factual and informative nature; or
- correspondence, which may be accompanied by material of a non-promotional nature, answering a specific question about a medicinal product.

The law states that for advertising to occur that there is the 'dissemination or issue of that advertisement (a) orally; (b) in writing; (c) by means of an electronic communications network within the meaning of the Communications Act 2003; or (d) in any other way, and includes causing or procuring such publication by or on behalf of another person'.

According to the Blue Guide labelling and package leaflets are not considered advertising if they meet the requirements of Part 13 of the HMR.

The ABPI Code defines promotion as: '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'.

Medical devices

The ABHI Code does not define advertising, but lists various forms of advertising directed to HCPs and to which the ABHI Code is intended to apply, including: journals, brochures, leaflets, circulars, mailings, emails, text transmissions, social media sites, faxes and catalogues, as well as follow-up literature and other electronic or printed material and/or verbal communications, detail aids and other printed material used by representatives, posters and other promotional media in public places at HCP events, as well as moving images and audio recordings.

The PAGB Code for consumer advertising includes a similar list, which additionally comprises: advertorials, aerial promotions, cinema commercials, clam shell advertising, direct mail materials, non-statutory information and claims made on packaging, pay-per-click and sponsored search ads, promotional scripts for use by telephone helplines, PR materials hosted on the consumer facing section of a website, materials which refer to sponsorship, but not the sponsorship itself, sales promotions, social media, television and radio commercials, viral advertising and materials written by a third party in relation to which the company has been asked to comment. The PAGB Code does not apply to genuine user generated content or to PR activities after the company's press release has been passed to a journalist.

3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?

Medicines

The MHRA enforces the HMR, but has an agreement with the ABPI such that the ABPI's enforcement arm, the PMCPA, may alternatively handle enforcement of advertising and promotion laws if the accused is willing for them to do so. Nevertheless, where criminal activities are involved, or if a company is under the jurisdiction of the MHRA (such as for new medicines or if there have been past breaches), then the MHRA will take the case.

The Bribery Act (applicable to inducements and hospitality) is enforced by the Serious Fraud Office.

The PMCPA enforces the ABPI code.

The PAGB enforces its consumer codes for its members.

<p>Medical devices The MHRA is also the enforcement agency for medical devices where claims are made for devices which are not regulated or where the claims are outside the terms of their authorisation.</p> <p>The ABHI Panel will rule when a breach of the ABHI code has occurred and the company is a member.</p> <p>Consumer protection laws The Competition and Markets Authority (CMA) is currently required to apply to court for an enforcement order against a company infringing consumer protection law. However, upcoming powers will allow the CMA to fine companies up to ten per cent of their global turnover.</p> <p>The ASA will take action where its codes are breached.</p>
<p>4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, such as food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?</p>
<p>The only health claims that might be made for foods, foods for specific groups, and food supplements are those authorised on the applicable register: (1) for Great Britain, this is the GB Nutrition and Health Claims (NHC) Register; (2) for Northern Ireland, this is the EU Register of Nutrition and Health Claims.</p> <p>Members of PAGB are required to submit any food supplement advertising for approval.</p>
<p>CONSUMER MARKETING</p>
<p>5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisements) in your country and, if so, which ones?</p>
<p>Medicines Prescription-only medicines cannot be advertised directly or indirectly to the public in the UK.</p> <p>Medical devices There are no restrictions on the promotion of any type of medical device to the public in the UK.</p>
<p>6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?</p>
<p>Medicines <i>Prescription-only medicines</i> Prescription-only medicines cannot be promoted to the general public. This means that all activity on the internet and social media must be carefully managed to avoid an accusation of 'advertising to the public' any content that relates to prescription-only medicines.</p> <p>Advertising to doctors via social media is permitted if all other applicable rules are complied with. This requires 'signposting' – stating the intended audience and then obtaining the individual's positive confirmation that they are a physician. If the content leads to an event for in-person or virtual attendance, then more formal validation might be required (PMCPA social media guidance 2023) (PMCPA SM Guidance). The PMCPA SM Guidance also requires that companies ensure that content is appropriate for the audience and suggests that when correcting inaccuracies of third parties, it might be preferable to link to reference documents (such as the Summary of Product Characteristics (SmPC)) rather than to point to sections of those documents to avoid an accusation of advertising a prescription-only product. Under the PMCPA SM Guidance companies are required to deal with pharmacovigilance issues arising from material on any of the sites that they directly or indirectly control. For compliance purposes links to other sites that are included in posts will be considered and assessed as part of the post.</p> <p>Influencers Scientists, HCPs and celebrities cannot be used as influencers for medicines. Companies should therefore avoid forwarding or 'liking' celebrity posts about their medicine. If influencers are used, they must be transparent about their relationship with the company, but also not promote prescription-only medicines.</p>

Medical devices

The use of social media for the advertisement of medical devices is generally permitted.

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

Medicines

The MHRA vets advertising materials only for certain products for a period of one to six months. These are:

- newly authorised product subject to additional monitoring;
- new active substances;
- product reclassified eg, from prescription-only to pharmacy only; and
- where previous advertising for a product has breached the relevant regulations.

The PAGB approves members' advertising copy for medicines and food supplements.

Medical devices

There is no prior approval from regulators for advertising of medical devices unless there has been previous wrongful advertising, when the MHRA might review adverts.

Consumer advertising

Advertising that is to be broadcast is subject to pre-clearance by Clearcast (a non-government organisation which pre-approves most British television advertising).

8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?

Unauthorised pharmaceuticals, unauthorised medical devices and off-label information on either product type may not be promoted under any circumstances.

9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?

Medicines

Where permitted, companies might only make comparisons that are fair, accurate, not misleading, balanced, objective, unambiguous and substantiated.

The public

Comparative claims to another named product are banned in adverts to the public, but claims relating to a category of products are permitted. The PAGB Code does not permit comparisons denigrating another product or product category and requires that companies make comparisons only where the difference is significant enough to be meaningful to consumers. Companies should avoid hanging comparisons.

Professionals

Companies might only make comparative claims that:

- relate to the licensed use;
- can be substantiated; and
- are either included in the SmPC or are not inconsistent with the SmPC.

Medical devices

Companies may make comparative claims for medical devices subject to general advertising laws. These require that comparisons are fair, accurate, not misleading, balanced, objective, unambiguous and substantiated. Companies should ensure that comparisons are of one or more material, relevant, substantiable, verifiable and representative features for devices meeting the same needs or for the same intended purpose.

The ABHI Code requires that companies must present clear evidence in a balanced manner to support comparative claims, including patient numbers whenever possible. Competitors' brand names should not be used without permission of the owner. Where a comparative claim is made in a context that allows a competitor to be identified, advertisers should provide information enabling the consumer to verify the claim.

DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS
10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?
<p>Medicines In the UK, the regulations refer to 'persons qualified to prescribe or supply', defined as persons who in the course of their profession or business sell or supply medicinal products.</p> <p>The ABPI Code defines healthcare professionals as: 'any member of the medical, dental, pharmacy or nursing profession and any other person who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine'. In relation to transparency rules, HCPs employed by a pharma company are also included.</p> <p>Medical devices The ABHI Code defines a healthcare professional as: 'any individual (with a clinical or non-clinical role; whether a government official, or employee or representative of a government agency or other public or private sector organisation; including but not limited to, physicians, nurses, technicians, laboratory scientists, researchers, research co-ordinators or procurement professionals) that in the course of their professional activities may directly or indirectly purchase, lease, recommend, administer, use, supply, procure or determine the purchase or lease of, or who may prescribe health technologies or related services'.</p>
11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?
<p>Medicines PMCPA cases show the following rules applying to virtual meetings: companies must ensure delegates are appropriate to attend, make it clear that the meeting promotes a medicine, include access restriction on attendance, inform delegates that they should be in a location where their screen cannot be readily visible to the public, make prescribing information available and provide time to read it, as well as providing prescribing information in a direct click link.</p> <p>Note that companies should also be advised to follow the EFPIA Joint Guidance on Virtual and Hybrid International Medical Congresses.</p> <p>Medical devices The same rules apply to virtual events as other activities with HCPs.</p>
12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how may such endorsements take place?
<p>Medicines As stated above, HCPs cannot endorse products in advertising of medicines to the public. There is no similar restriction however on their providing testimonials for medicines being advertised to other persons permitted to prescribe or supply those medicines.</p> <p>Medical devices There are not specific restrictions on endorsements by HCPs in advertising medical devices. The CAP code for advertising to the public requires that HCPs endorsing products must be suitably qualified to make that endorsement.</p>
13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.
<p>Medicines Companies are permitted to provide samples to individuals qualified to prescribe the specific product to allow that person to acquire experience in dealing with that product. However, this must be on an exceptional basis, in response to a written dated request, limited by number in that year, for a sample no</p>

larger than the smallest available presentation, marked 'free medical sample – not for resale' or similar, be accompanied by the SmPC, and not be for a narcotic or psychotropic substance.

The ABPI Code additionally requires that companies: provide no more than four samples per medicine per year to an individual and provide these for no longer than two years after the first request, and that companies secure samples to be sent by post against opening by young children and do not provide samples as an inducement.

Medical devices

There are no laws governing the provision of medical device samples, however companies should bear in mind the general rules on safety and liability for products.

The ABHI Code permits companies to provide demonstration products (not intended for clinical use) and samples on an exceptional basis as long as this is not an inducement. Companies must maintain records on the provision of demonstration products and samples and make it clear to the recipient that the provision is on a no-charge basis. Companies should limit samples to the number necessary for the HCP to familiarise themselves with the device if a single use product. For multiple use products, provision must be on a time limited basis for the duration necessary for familiarisation based on anticipated use and the company must retain title to the device and ensure it is returned within the period determined to be appropriate.

Both

Companies must maintain records and have adequate systems of control over distribution of demonstration products and samples to comply with the above rules.

14. What rules govern the offering of hospitality to healthcare professionals?

Healthcare professionals generally

Companies should be mindful to avoid interactions with HCPs which might be considered an inducement to prescribe or supply a medicine or a medical device. This would be a breach of the UK's Bribery Act 2010. The NHS also has rules on managing conflicts of interest which apply to their employees and contractors which require them to notify their employer of interactions with industry which could be construed as a conflict of interest. For both medicines and medical devices, it is prohibited to provide entertainment or gifts to HCPs.

Medicines

UK medicines laws specifically prohibit companies inducing a person qualified to prescribe or supply a medicine by providing any benefit to them. Companies must strictly limit hospitality at promotional events to the main purpose of the meeting or event.

Medical devices

The ABPI Code permits 'reasonable hospitality' (meals and accommodation) at company events and third party organised events if it is subordinate in time and focus to the event purpose.

15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?

Medicines

Under the ABPI Code companies may give donations to institutions, but not to individuals. Donations must only support: healthcare, scientific research or education. Companies may only give donations prospectively and must have a specific and certified written agreement and keep a written record. Donations must be disclosed annually.

Medical devices

Under the ABHI Code, companies may only give donations to institutions and not individuals. Companies cannot make donations to institutions if the request originated from an individual HCP unless they submit a written request on behalf of the institution. Companies should have an independent decision-making review process for all donations and all donations should be documented.

16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?

Medicines

<p>The ABPI Code permits the support by companies of individual HCP attendance at scientific or educational meetings. Companies are required to ensure that there is clear educational content with a programme including appropriate content that will attract delegates (rather than the location or hospitality being the attraction). The company should not pay for any entertainment or sporting or leisure activities.</p> <p>Medical devices The ABHI Code does not permit companies to support individual HCP attendance at scientific or educational meetings, but companies may provide a grant to fund unspecified individuals as recipients of that funding.</p>
<p>17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.</p>
<p>Medicines Companies are required to have robust procedures to ensure that when interacting with patient organisations these might retain their independence. The ABPI Code requires that companies do not influence the content of patient organisation materials except for contributions that provide a fair and balanced scientific perspective. Companies must have a written agreement for all donations and grants to patient organisations, and these interactions must be publicly disclosed including monetary value of the support as well as fees and expenses paid to individuals representing patient organisations. Companies are not permitted to provide gifts to individuals associated with patient organisations.</p> <p>Medical devices Companies in the UK might choose to refer to the MedTech Europe Guidance on the interactions between the medical technology industry and patients' organisations.</p>
<p>18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?</p>
<p>While promotional activities might be delegated to third parties by contract, companies remain responsible for compliance of the materials produced by those third parties with the laws and codes which apply to them. There is no specific regulation for co-promotion activities in the UK.</p>
<p>19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?</p>
<p>UK law does not require companies to report transfers of value to HCPs. The ABPI Code does however include such a requirement for its members and any other companies which sign-up to their Code.</p>
<p>ENFORCEMENT</p>
<p>20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?</p>
<p>The MHRA has the power to issue compliance notices, restriction notices and potentially unlimited fines. Prosecution for individuals could carry a penalty of an unlimited fine and/or six months' imprisonment. The MHRA will engage with any company that is breaching the laws, unless the PMCPA is handling the matter, but the MHRA will generally only prosecute in the event of an intentional and significant breach of the law. Companies that breach the law through ineptitude or a failure to understand the parameters of the advertising laws and which then correct their advertising are not usually prosecuted.</p> <p>The PMCPA will rule where complaints are made against an ABPI member or, if they are not a member, they agree to be subject to the PMCPA jurisdiction. The alternative for pharma companies is a referral to the MHRA. The PMCPA can issue administrative sanctions and, if a clause 2 breach, which is the most serious, can expel the company from the ABPI. All PMCPA final decisions are made public.</p> <p>The ABHI Panel will rule when a breach of the ABHI code has occurred. Enforcement mechanisms include issuing a formal reprimand, recommending expulsion from the ABHI and ordering the party to pay the costs of the ABHI Panel.</p> <p>The CMA is currently required to apply to court for an enforcement order against a company infringing consumer protection law. However, upcoming powers will allow the CMA to fine companies up to ten per cent of their global turnover.</p>

The ASA will take action where its codes are breached. Enforcement powers range from flagging non-compliant companies on search engines to referring ongoing non-compliant companies to Trading Standards, who can seek criminal prosecution or confiscation of financial assets.

The UK law does not provide for damages actions by competitors for a breach of advertising laws.

21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?

See the response to Question 20, above.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

Medicines

Advertising laws and regulator guidance with respect to medicines are relatively well developed in the UK and are not expected to change. The ABPI Code will be updated in 2024.

Medical devices

New laws for medical devices are being developed and will be published during 2024. We anticipate that they might include new provisions on advertising medical devices similar to those in the EU laws.

Transparency

The government is expected to present new laws requiring both medicine and medical device companies to provide publicly details of interactions with HCPs and patient organisations. No date for this has been published.