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PHARMACEUTICAL ADVERTISING

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This country-specific Q&A provides an overview of pharmaceutical advertising laws and regulations applicable in United Kingdom.

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UNITED KINGDOM
PHARMACEUTICAL ADVERTISING

1. What laws are used to regulate advertising on medicines in your jurisdiction?

Part 14 of the Human Medicines Regulations 2012/1916, as amended ("**Regulations**") provides the general legal framework for the advertising of medicines in the UK. The Regulations continue to implement into UK law the

provisions of EU Directive 2001/83/EC in its form immediately prior to the end of the Brexit transition period (31st January 2021). The Regulations are applicable to any person, Marketing Authorisation Holder ("**MAH**") or any third party such as a journalist or public relations agency. The Medicines and Healthcare products Regulatory Agency ("**MHRA**") supervises the advertising of medicinal products on behalf of the licensing authority. MHRA publishes supplemental guidelines to the Regulations, currently in the form of the Advertising and Promotion of Medicines in the UK (November 2020) (the "**Blue Guide**") and general guidance on the MHRA website.

The Cancer Act 1939 prohibits any advertisement to the public that contains an offer to treat any person for cancer, or to prescribe any remedy for its treatment, or to give any advice in connection with the treatment of the condition. This Act is administered and enforced by the Trading Standards Service.

In addition to the legislation specifically relating to medicines there is general legislation on advertising, which may be relevant. For example, The Trade Descriptions Act 1968 and the Consumer Protection from Unfair Trading Regulations 2008 regulate consumer advertising generally, including the advertising of medicines.

2. Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?

Yes. A number of self-regulatory codes of industry bodies regulate the advertising of medicines. The Codes of Practice essentially repeat the law, however in several respects, they provide more detail. The majority of pharmaceutical companies operating in the UK opt to comply with a self-regulatory code, whether they are members of the relevant industry association or not..

The Association of the British Pharmaceutical Industry Code of Practice ("**ABPI Code**"), administered by the Prescription Medicines Code of Practice Authority ("**PMCPA**"), governs the advertising of prescription only medicines ("**POM**"). The ABPI Code is updated regularly and the latest version came into operation on 1 July 2021.

The Proprietary Association of Great Britain ("**PAGB**") Consumer Code governs the advertising of over-the-counter medicines ("**OtCMs**") to the general public. All advertising aimed at consumers must be submitted to PAGB for screening and PAGB approval must have been given prior to its release into the public domain. The PAGB Professional Code governs the advertising of OtCMs to persons qualified to prescribe or supply. The PAGB Codes apply to advertising for all OtCMs regardless of their route to market approval or traditional herbal medicines registration.

The Advertising Standards Authority ("**ASA**") sets the general standards required of all advertising in the UK and administers the broadcast ("**BCAP**") and non-broadcast ("**CAP**") advertising codes. ASA is an independent body, responsible for ensuring that the system operates in the public interest. In addition to the general requirements, Section 12 of the CAP Code contains provisions specifically relating to medicines; the BCAP Code contains similar rules in Section 11. It should be noted that the CAP Code does not apply to health

claims in materials aimed at health professionals.

The ASA proactively checks for adherence to the required standards and has dealt with a number of cases relating to the advertising of medicines, particularly botulinum toxin products (including Botox) and homeopathic medicines, including advertising on social medial platforms.

a. If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)?

All companies which are ABPI members are required to comply with the ABPI Code and accept the jurisdiction of the PMPCA as a condition of membership. The PMCPA, which operates independently of the ABPI, administers the ABPI Code and provides advice, guidance and training. In addition, most of the other companies operating in the UK which are not members of the ABPI give their formal agreement to abide by the ABPI Code in their promotional activities. The ABPI Code covers the medical industry's activities only, but those interacting with industry such as public relations agencies have a responsibility to ensure that their interactions comply with relevant legal requirements, and are asked to follow the ABPI Code where relevant and not to make requests that would breach the ABPI Code. It is a condition of PAGB membership that all members comply with the PAGB Codes both in letter and in spirit. The PAGB Consumer Code notes that materials written by a third party and which mention a company's brands are regarded as advertisements, and it is the responsibility of the member company to ensure that such materials are "factually accurate, consistent with the relevant SmPC(s) and fully compliant with the Code".

b. What is the legal status of the self-regulatory codes?

Alleged breaches of the ABPI Code are referred to the PMCPA's Code of Practice Panel, which has the power to impose fines and other sanctions if a breach of the Code is upheld. A decision of the PMCPA's Code of Practice Panel may be appealed to the Code of Practice Appeal Board. Where a company is found in breach, it must give an undertaking (accompanied by details of the action taken) that the practice in question has ceased forthwith and that all possible steps have been taken to avoid a similar breach in future. Administrative charges are also payable. Case reports are published once cases are concluded.

Additional sanctions are imposed in serious cases, which can include the audit of a company's compliance procedures, a requirement for the pre-vetting of future material, recovery of material from those to whom it has been given, the issue of a corrective statement or a public reprimand. A company may also be required to publish brief details of cases in the medical, pharmaceutical and nursing press if it was ruled that the company (i) breached clause 2 of the ABPI Code; (ii) had to issue a corrective statement or was the subject of a public reprimand; or (iii) is suspended or expelled from the ABPI.

The PAGB does not impose financial sanctions for a breach of the PAGB codes, but a company may be expelled from the PAGB for failure to comply. PAGB also runs a post-publication complaints system for advertising aimed at persons qualified to prescribe and supply. PAGB does not adjudicate on formal complaints about member companies' consumer advertising, as it will have approved the advertising prior to publication, but these are handled as informal queries. If a complaint filed with the ASA is upheld, the ASA asks the advertiser to withdraw or amend the advertising. Broadcasters are obliged, by a condition of their Ofcom licences, to enforce ASA rulings and not to run advertisements which breach the codes. Ofcom is able to levy fines and revoke licences in particularly serious cases of non-compliance. If non-broadcast advertisers do not comply with adjudications, CAP can issue an 'Ad Alert' to request those responsible for accepting ads for publication to consult CAP's Copy Advice team before accepting any ads from the named advertiser. If advertisers do not co-operate with the self-regulatory system, the ASA can refer them to Trading Standards Services, which acts as a legal backstop in cases of repeated non-compliance. Publication of the results of adjudications on the ASA website can generate adverse publicity for those in breach of the codes, and persistent breaches can lead to disqualification from trade associations.

Ultimately, the system of self-regulation is supported by the MHRA, which has a clear role and acts on behalf of Health Ministers to protect public health by promoting the safe use of medicines. Complaints about advertising can be received by the MHRA and/or a self-regulatory body, and the MHRA works closely with these bodies and other statutory regulators to ensure a consistent approach on advertising standards. The Medicines Advertising Liaison Group provides a forum for cooperation.

The MHRA would not normally investigate cases where these are already under investigation by another self regulatory body. It could, however, take action if serious public health concerns are raised or if self-regulation fails, for example in cases of repeated non-compliance. A Memorandum of Understanding sets out the relationship between the PMCPA process and the supervisory and enforcement function of the MHRA. The MHRA usually passes inter-company complaints referred to it on to the PMCPA, and may refer other complaints to the PMCPA

with the complainant's consent.

The MHRA has the power to issue notices requiring a person not to publish, or to cease publishing, an advertisement; if that person then publishes the advertisement in breach of the notice, he or she commits a criminal offence. There are also rules under which the publication of a corrective statement may be required. Advertising cases tend to be resolved informally and prosecutions are not common.

3. Is there a statutory or generally accepted definition of "advertising"? a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

Yes. "Advertisement" is broadly defined in Article 7 (1) of the Regulations as "anything designed to promote the prescription, supply, sale or use of that product."

a. What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example?

The Regulations specify that the definition of "Advertisement" includes:

i. door-to-door canvassing;

ii. visits by medical sales representatives to persons qualified to prescribe or supply medicinal products;

iii. iii. the supply of samples;

iv. the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except where the intrinsic value of such inducements is minimal;

v. the sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products; and vi. the sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products, including the payment of their travelling and accommodation expenses.

However, the Regulations clarify that "Advertisement" does not include:

i. a medicinal product's package or package leaflet;

ii. reference material and announcements of a factual and informative nature, including:

a. material relating to changes to a medicinal product's package or package leaflet,

b. adverse reaction warnings,

c. trade catalogues, and

d. price lists, provided that no product claim is made; or

iii. correspondence, which may be accompanied by material of a non-promotional nature, answering a specific question

The ABPI Code does not define "advertising", but uses the term "Promotion" instead. "Promotion" under the ABPI Code means "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 1.17). The ABPI Code also provides a comprehensive list of specific activities which are considered to fall within the definition of Promotion and those which should not. The PAGB Codes also contains detailed lists of examples of the various formats that advertising can take (again, a broad interpretation is adopted), together with lists to clarify what is not regarded as falling within the scope of the Code.

b. Does the definition apply equally to all target audiences?

The Court of Justice of the European Union ("CJEU") has provided some clarification on who is subject to the advertising rules under the statutory definition of "advertising". In the Damgaard case (C-421/07), the CJEU ruled that 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. However, regarding the rules relating to inducements to prescribe, the CJEU has held that national public health authorities may lawfully offer incentives to doctors to prescribe certain medicines in preference to others when pursuing public health policy, including any policy on the public expenditure on pharmaceuticals (Case C-62/09 ABPI).

Furthermore, the CJEU concluded that the dissemination of information that is a faithful and complete reproduction of the approved package leaflet or summary of product characteristics ("**SmPC**") of a medicinal product is unlikely to be considered advertising, although a selection of extracts or rewriting

of any such information, which can be explained only by an advertising purpose is prohibited (Case C-316/09 MSD).

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

The Blue Guide contains a section clarifying the position regarding press releases. The starting point is that press releases, such as those released at the time of launch of an innovative product, should not be used to promote a POM. Any information provided to the lay press, television or radio or by press release must be factual and non-promotional, without encouraging the general public to ask their GP to prescribe the product. Use of brand names should be kept to a minimum. The MHRA considers that press releases should be genuinely newsworthy. Particular care should be taken in providing information in response to direct approaches from the media, which could result in the promotion of POMs to the general public.

Clause 26 of the ABPI Code covers relations with the public and the media. The ABPI Code allows for the provision of non-promotional information about POMs to the public either in response to a direct enquiry from an individual, including enquiries from journalists or by dissemination of such information via press conferences, press announcements, television and radio reports etc. The ABPI Code recommends including the SmPC with a press release, and where appropriate, including references to other credible sources of information about a condition or a medicine.

To promote balanced media coverage, press releases should provide the context in which the medicine will be used and the population for which it has been licensed. The material included should be appropriate for the target audience and written in terms likely to be understood by the majority of readers.

Companies may provide appropriate information to the UK business and financial press in line with their obligations to keep shareholders or other investors fully aware of developments which may impact their UK share price. Business press releases should identify the commercial importance of the information and be factual and balanced.

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?

Companies are free to decide their own internal procedures and guidelines for reviewing and approving promotional material relating to medicines. However, the final form of all promotional material must be certified by a nominated person on behalf of the company before it is disseminated. All promotional materials must be certified, regardless of format (e.g. printed or electronic, audio and audio-visual).

Promotional materials which will be printed in hard copy can be certified in electronic form by a company signature. However, the company signatory must check and sign the item in its final printed form before it is used.

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. The signatory must not be the same person who was responsible for creating the content.

Promotional 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 promotional material.

6. Do companies have to have material approved by regulatory bodies prior to release?

From a UK perspective, advertised medicines themselves must be authorised by the MHRA before being advertised. Under Article 279 of the Regulations an advertised medical product must have received one of the following: a Marketing Authorisation, a certification of registration (pursuant to Article 127 of Directive 2001/83/EC), an authorisation by the licensing authority on a temporary basis, a traditional herbal registration or an Article 126a authorisation (i.e. herbal registration where a vitamin or mineral has been added).

The Regulations do not generally require the advance approval of the materials used to advertise the medicine. However for the following specific products Article 304 of the Regulations gives the MHRA the statutory power to request copies of advertisements prior to publication and not to use those advertisements until they have been approved:

i. where a newly authorised product, subject to

additional monitoring, is placed on the market;

ii. where a product is reclassified; or

iii. where previous advertising for a product has breached the Regulation.

It is a criminal offence to fail to comply with such a notice.

As a matter of policy the MHRA has decided to vet all advertising of new active substances. The MHRA will usually take one week to review and approve the advertising, but depending on the information provided it may take up to three months to six months. Either way, the MHRA will inform the licence holder of the estimated timing for the vetting.

The ABPI Code does not require any prior approval for the advertising of POMs, but guidance can be sought prior to publication. MHRA vetting does not guarantee compliance with the ABPI Code. In the case of OtCMs, 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). Any advertising material intended for non-broadcast media comply with the CAP Code; similarly, advertising material intended for television or radio must also comply with the BCAP Code.

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

Article 287 of the Regulations sets out the general principle that advertising to the general public must not suggest that the effects of taking a product are "better than or equivalent to those of another identifiable treatment or medicinal product". The Blue Guide confirms that comparative claims for a medicine against another named product (such as "works faster than XXX") are prohibited, although this is not applicable for category claim such as "works faster than standard tablets", provided there is supporting evidence. Claims suggesting that a product is as good as the best (such as "nothing acts faster than …") are not prohibited, but care should be taken that consumers are not misled. Similarly, claims that a product has been manufactured in such a way as to make it purer or otherwise of better quality to a similar product should not mislead.

POMs

Clauses 6 and 14 of the ABPI Code set out restrictions on the extent to which comparisons between products may be made. In general, all comparisons must be capable of substantiation and must be "accurate, balanced, fair, objective and unambiguous". They must not mislead "either directly or by implication, by distortion, exaggeration or undue emphasis".

A comparison is only permitted in promotional material if it fulfils the following conditions:

- it is not misleading;
- medicines or services for the same needs or intended for the same purpose are compared;
- one or more material, relevant, substantiable and representative features are compared;
- no confusion is created between the medicine advertised and that of a competitor or between the advertiser's trade marks, trade names, other distinguishing marks and those of a competitor;
- the trade marks, trade names, other distinguishing marks, medicines, services, activities or circumstances of a competitor are not discredited or denigrated;
- no unfair advantage is taken of the reputation of a trade mark, trade name or other distinguishing marks of a competitor; and
- medicines or services are not presented as imitations or replicas of goods or services bearing a competitor's trade mark or trade name.

The use of other companies' brand names when making comparisons is not excluded. However, Clause 6.6 of the ABPI Code prohibits the disparagement of another pharmaceutical company's products or activities. The ABPI Code contains more detailed guidance, including examples of the sorts of comparative claims where particular care must be taken.

Equally, company representatives must not make claims or comparisons which are in any way inaccurate, misleading, disparaging or in poor taste, since all provisions in the ABPI Code relating to the need for accuracy, balance, fairness, good taste etc. apply to oral representations as well as to printed and electronic material.

OtCMs

Section 1.5.5 of the PAGB Professional Code addresses comparative advertising, the main principles being:

- All comparisons shall be balanced, fair and supportable
- Comparisons shall not denigrate or discredit, either directly or by implication, a competitor product, ingredient or treatment type, nor mislead the recipient

- "Hanging comparisons" (i.e. one which begs the question 'compared to what?' e.g. "faster pain relief" / "better ..." / "stronger ...") shall not be used
- "Top parity" claims (i.e. those that imply that no one product has superiority in a given area, such as efficacy, speed of action, duration of action, etc. e.g. "nothing is proven to work better/faster/longer") are only acceptable when they are supported by positive evidence; studies must show that no other product within the same therapeutic category is superior to the one being advertised. (The PAGB Consumer Code also contains detailed advice on making "top parity" claims, along similar lines, and PAGB has published a "Guideline on the Use and Substantiation of Top Parity Claims").
- Superiority claims are not acceptable unless supported by direct comparative tests or similar.
- The PAGB Consumer Code requires that superiority claims for OtCMs made in consumer-directed advertising must also be supported by direct comparative tests or other demonstrations as appropriate. Care must be taken when making such claims as products within a therapeutic category are often licensed as offering the same degree of relief (such as the expression "mild to moderate pain"). It is unusual for PAGB to agree to a superiority claim, such as the expressions "the best", "the fastest", "the strongest". Also, "the" is regarded as a superiority claim and PAGB advises changing the word "the" to "a" or "an". Claims based on sales data must be carefully worded to avoid implying clinical superiority.

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

The rule is that a medicine must not be promoted prior to the grant of a Marketing Authorisation (or traditional herbal registration, homoeopathic medicinal product certificate of registration or "Article 126a authorisation" (for justified public health reasons), where appropriate). Similarly, it may not be promoted for indications for which it is not authorised (Article 280 of the Regulations) or where it has temporary approval it may not be promoted unless part of an approved campaign; see also Clause 3 of the ABPI Code and Sections 1.5.1 of the PAGB Codes. It is a criminal offence to promote an unlicensed medicine or unauthorised indication under the Regulations and the Blue Guide highlights that "robust enforcement action" will be taken where advertising of unlicensed medicines poses a significant risk to public health.

However, the provision of information about an unauthorised medicine or unauthorised indication may be permitted if it falls within an exemption to the general rule. For example, the Blue Guide clarifies that providing a factual, non-promotional answer to an unsolicited question about an unlicensed medicine, or about use of a licensed medicine outside the terms of its licence ("off-label" use) is permitted, although any activity that appears to be designed to solicit such questions would be likely to be considered promotional and therefore prohibited.

Companies may also provide information at international meetings organised by learned societies and give advance notification of new products to the National Health Service ("NHS") or where information is required by national public advisory or horizon scanning bodies (see below). The legitimate exchange of medical and scientific information during the development of a medicine is permitted.

Licensed manufacturers and suppliers of unlicensed medicines ("specials") must not advertise specific unlicensed products but may, at reasonable intervals or in response to an enquiry, send out price lists to healthcare professionals to whom the price of specials may be relevant. The MHRA advises that any price list supplied in relation to an unlicensed medicine should consist only 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; product claims are not permitted. As a general rule, such communications must make clear that the products are unlicensed. The Blue Guide provides that material relating to products or indications unlicensed in the UK may be displayed or made available on request at international symposia, conferences etc. of high scientific standing provided that:

- a significant proportion of the attendees are from countries outside the UK where the product or indication is licensed (this should include at least one major developed

country); and
- the material is relevant, proportional to the purpose of the meeting, and clearly indicates that the product is unlicensed in the UK.
- Information of genuine scientific interest, including press releases, may be provided in relation to both unauthorised medicines and unauthorised indications, provided that that is not promotional; the tone and content must be accurate, factual and balanced. If the publication has been sponsored by a pharmaceutical company, this must be clearly indicated.

The need for the NHS, and others involved in purchasing medicines, to be able to plan ahead in terms of likely budgets is recognised in the ABPI Code.

Information concerning new medicines, or changes to existing ones, which may significantly impact on levels of expenditure, 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 (see Clause 3.1 Supplementary Information of the ABPI Code). The information must be non-promotional / factual and must only be directed to those responsible for making policy decisions on budgets and not those expected to prescribe.

The likely cost or savings and budgetary implications (which must be such that they will significantly change the organisation's likely expenditure) must also be provided. The MHRA Blue Guide also notes that such information may be provided "exceptionally".

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, an indication of the information that must or must not be included.

Article 284 of the Regulations prohibits advertisements that are likely to lead to the use of POMs, other than in campaigns relating to the spread of pathogenic agents and for approved vaccination campaigns. However, it is possible to provide non-promotional information regarding POMs to the public if it is 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.) (clause 26.2 of the ABPI Code). 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.

OtCMs may be advertised to the general public provided that the advertisement encourages the rational use of the product by presenting it objectively, without exaggerating its properties and it must not be misleading. The advertisement must also be presented in such a way that it is clear it is an advertisement with the product clearly identifiable as a medicinal product; show the name of the medicinal product; include the name of the active ingredient; any information necessary for the correct use of the product; and a clear invitation to read the instructions carefully.

Articles 280 to 293 of the Regulations set out further restrictions on advertising. 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; and/or
- be directed principally at children.

10. Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.

The Blue Guide states, in Chapter 5 (Advertising to the Public), that "sponsorship linked to a brand of medicine would be acceptable in principle for products classified as over-the-counter". It goes on to clarify that where any manufacturers or pharmaceutical companies sponsor a medicine, the advertisement "should not include any promotion of prescription-only medicines".

Clause 27 of the ABPI Code governs relationships with patient organisations. Clause 27.1 states that "when pharmaceutical companies interact with patient organisations or any user organisations such as disability organisations, carer or relative organisations and consumer organisations, companies must [...] respect the independence of patient organisations ...". This clause contains additional rules for the interaction between patient organisations and the industry. However, in the interest of brevity, only two of the more prominent sub-clauses are included below:

27.2: When companies provide donations, grants or sponsorship (including in relation to events/meetings) to patient organisations as set out in Clauses 23.2 and 10, companies must have a written agreement in place for each donation, grant or sponsorship setting out exactly what has been provided.

27.5: Companies can contract with patient organisations or individuals representing patient organisations under which they provide any type of service to companies providing these comply with Clause 24." Clause 24.3, in turn, provides as follows:

"Contracts between companies and health professionals, other relevant decision makers or their employers on their behalf, healthcare organisations, patient organisations, individuals representing patient organisations, and members of the public, including patients and journalists under which they provide any type of service (not otherwise covered by the Code) to companies are allowed providing such services: are provided for the purpose of supporting healthcare, research or education; and do not constitute an inducement to recommend and/or, prescribe, purchase, supply, sell or administer a specific medicine."

In general, Clause 27 is designed to ensure maximum transparency of any industry involvement with patient organisations, thereby trying to limit the influence that it may have upon any such organisations.

The PAGB Consumer Code states that corporate sponsorship may include the umbrella name of the brand so long as no claims are made alongside the name. The PAGB Consumer Code goes on to state that sponsorship of television programmes, events and certain educational materials is also possible although it would need to abide by the Code's other rules.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example can information about clinical trials, or copies of journal be sent?

In accordance with Article 294 and Schedule 30 of the Regulations, all advertisements, excluding Abbreviated Advertisements (see below), to healthcare professionals must contain the following information:

i. A UK or EU marketing authorisation number

ii. The name and address of the marketing authorisation holder, or temporary marketing authorisation holder (or that part of the holder's business that is responsible for the product's sale or supply).

iii, in relation to medicinal products authorised under a UKMA(GB), a statement that the product concerned is authorised under a UKMA(GB)

iv. The classification of the medicinal product (i.e. POM, P or GSL).

v. The name of the medicinal product.

vi. 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.

vii. One or more of the product's indications for use, consistent with the terms of its marketing authorisation, or where the product has temporary authorisation under Regulation 174 – the indications for the product consistent with the recommendation or requirement of the licensing authority as to the use of that product.

viii. A succinct statement of the entries in the product's SmPC relating to (i) adverse reactions, precautions and relevant contraindications, (ii) dosage and method of use, and (iii) method of administration (where not obvious).

ix. The cost (excluding VAT) of the product.

Different rules apply to "Abbreviated Advertisements"

which are defined in Article 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”. Such advertisements must the majority of the information required for a full advertisement (as listed above), but it 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.

Advertisements to healthcare professionals must also contain information which is compatible with the SmPC. The CJEU provided further clarity on this point in the Novo Nordisk case (C-249/09) where they established 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. This is reflected in Clause 11.2 of ABPI Code which 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]”.

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?

Article 300(1) 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 (i) inexpensive and (ii) relevant to the practice of medicine or pharmacy.

Paragraph 6.15 of the Blue Guide sets out guidance on the interpretation of “inexpensive” and “relevant” and confirms that “both conditions must be satisfied.”

Inexpensive: “those which do not cost a company more than GBP 6 (excluding VAT) and represent a similar value to the recipient”;

Relevance: “only met by items which have a clear business use and may include such items as pens, notepads, calculators, computer accessories, diaries, calendars, surgical gloves, tissues and coffee mugs”.

The Blue Guide contains an explicit warning that breach of Article 300(1) of the Regulations is a criminal offence. It is also an offence for any person qualified to prescribe or supply medicinal products to solicit or accept any gift, pecuniary advantage or any benefit in kind in breach of this provision.

For POMs, the ABPI Code is more restrictive than the Regulations: any gift to health professional or other relevant decision-makers is prohibited as a rule, save in exceptional circumstances. The ABPI Code carves out three main exceptions to this rule and allows for:

i. Inexpensive promotional materials provided at events to the attendees (Clause 10.4), i.e. a set of notebook and pen or pencil each, for a total costs not exceeding £6 (excluding VAT) per individual and the perceived value by the recipient must be similar;

ii. the provision of information support DVDs or memory sticks for educational or promotional material if the support cannot be used to store other data, respectively, is commensurate with the amount of data to be stored (Clause 19.1 Supplementary Information);

iii. information material to be passed on to patients, which will not be consider promotional if it is limited to “leaflets, booklets and textbooks about medicines and their uses” (Clause 19.1 Supplementary information; see also “patient support items” (Clause 19.2 Supplementary information).

Apart from these exceptions, according to the ABPI, any items (also referred to as “promotional aid”, i.e. a “nonmonetary gift made for a promotional purpose”) provided must “directly benefit patient care”, and “be passed on to patients” as “part of a formal patient support programme” with appropriate documentation and certification. The ABPI also considerably restrict the modes through which, and the purposes for which, the items may be given out (Clause 19.2). Thus, items must not be provided from exhibition stands or to administrative staff. The ABPI (Clause 19.1 supplementary information) states that no item may be provided for the personal benefit of health professionals or other relevant decision makers, and also excludes items that would be used within the course of their business: “coffee mugs, stationery, computer accessories, diaries, calendars and the like are not acceptable”, or even as part of their clinical practice: “Gifts of items for use with patients in the clinic, surgery or treatment room etc., such as surgical gloves, nail brushes, tongue depressors, tissues and the like, are also not acceptable”.

Promotional aids must not bear the name or any information about any medicine, but may bear the name of the company providing them. If such items are included in conference bags provided at third party organised conferences, the gifts should not include the company name or the name of any medicine or any information about medicines

Paragraph 6.15 of the Blue Guide adds that the restrictions of the Regulations also apply to membership schemes and cumulative points schemes which have the effect of conferring benefits in the form of free or reduced price goods or services.

Finally, the National Health Service (NHS) (England) has also published the Standards of Business Conduct Policy (updated 2022) describing the standards and public service value which underpin the work of the NHS. 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.

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

Free samples are permitted under Article 298 of the Regulations provided that certain conditions are met. A first set of conditions relates to the person in receipt of the sample. The person must be qualified to prescribe medicinal products. Moreover, the person must receive the sample for the purpose of "acquiring experience in dealing with the product in question" (Condition A, Article 298(2)(a) and (b) of the Regulations). A sample must not be provided simply as an inducement to prescribe medicine, nor for the sole purpose of treating patients (Clause 21.10, ABPI Code). Medicines which are prescription-only must not be sold or supplied to members of the public for promotional purposes (Clause 21.9, ABPI Code). Of note, the Regulations also prohibits samples for OtCMs for promotional purposes being distributed to the general public by pharmaceutical

companies, including through pharmacy channels (Article 298 of the Regulations, Paragraph 5.9 Blue Guide)

second set of conditions relates to the amount in which the sample may be provided:

i. the sample must only be supplied "on an exceptional basis" and upon request (dated and signed) by the recipient (Condition B);

ii. only a limited number of samples may be provided in each running year (Condition C). This number is not directly defined in the HMR nor in the Blue Guide, but is left to self-regulation. The ABPI Code limits the number of samples to "no more than four samples of a particular medicine" to "an individual health professional during the course of a year" (Clause 21.2, ABPI Code). The ABPI Code further clarifies that samples of a particular medicine may be provided to a health professional for no longer than two years after the health professional first requests sample of it. An exception is made when a 'new' medicine is marketed which is an extension to an existing product. However, this supposes that a new marketing authorisation has been granted;

iii. the sample must be no larger than the smallest presentation available for sale in the UK, must be appropriately labelled and bear a mark stating "free medical sample – not for resale" (or similar description), and must be accompanied by an SmPC (Condition D).

Special restrictions apply to the supply of samples containing psychotropic or narcotic substances controlled under the Narcotic Drug Convention or Psychotropic Substances Convention. Providing samples for these medicines is prohibited as a rule, save for substances falling within certain categories of the Conventions (as listed in their Schedules I, II or IV, and not exempted under Schedule III of the Narcotic Drugs Convention; or Schedules I to IV of the Psychotropic Substances Convention, unless exempted under Art. 3(2) or 3(3) of the Convention). See Article 298(6) of the Regulations (Condition E).

Note that the Blue Guide explicitly states that the Department of Health does not recognise a special status to the so-called "starter packs" (i.e. short-term supplies provided for use in emergency situations, out-of- hours and in the patient's home). These are considered samples under the Regulations and are required to comply with the requirements applicable thereto (Paragraph 6.12 Blue Guide).

A final set of conditions relates to the organisation providing the sample: these organisations must have in place an adequate system of control and accountability for samples provided, as well as for all medicines handled by their representatives. The system must, in particular, allow the organisation to keep record of the number of samples supplied for each health professional (Clause 21.7, ABPI Code; Condition F).

14. Is sponsorship of scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

There are no restrictions on sponsoring scientific meetings or congresses as such, but restrictions on "providing hospitality" and other benefits at such events for health professionals apply. In Article 300(5) of the

Regulations, "Hospitality" includes:

a. "sponsorship of a person's attendance at a meeting or event; and

b. the payment of travelling or accommodation expenses."

The ABPI Code gives some more details on the elements that hospitality may include (Clause 10.1):

• Refreshment & subsistence (i.e. drinks and meals) with an upper limit of GBP 75 per person excluding VAT (Clause 10.7);

• Accommodation;

• Genuine registration fees;

• Generally speaking, hospitality is acceptable if it is strictly limited to the main purpose of the meeting. Thus, hospitality is only allowed, pursuant to Article 300(3), at an event "held for purely professional or scientific purposes" if:

a. "the hospitality is strictly limited to the main scientific objective of the event; and
b. The person to whom it is provided or offered is a health care professional."

The hospitality should "be reasonable in level" (Blue Guide Paragraph 6.16). The ABPI Code provides more information on the extent to which costs are considered acceptable. In particular, no costs can be covered for accompanying persons who do not themselves meet the criteria for a health professional (e.g. partners).

The Regulations makes no explicit reference to events abroad but the definition of the term "hospitality" includes payments of travelling or accommodation expenses. The ABPI Code clarifies that organising events involving UK health professionals at venues outside the UK is not unacceptable as such, but requires "valid and cogent reasons for holding meetings at such venues". A useful reference given in the ABPI Code is that "it should be the programme that attracts delegates and not the associated hospitality or venue" (Clause 10.1).

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

As noted above, the Regulations allow for the offering of hospitality within a scientific event provided that:

a. "the hospitality is strictly limited to the main scientific objective of the event; and

b. the person to whom it is provided or offered is a health care professional."

Therefore, if the "cultural, sports or other non-scientific events" is included within a scientific conference, the hospitality could be regarded as prohibited under Article 300(3), which precludes hospitality that is not "strictly limited to the main scientific objective of the event". The general requirement is thus that the hospitality is tied and strictly limited to the purpose of the event (either promotional or scientific). Events that are for the general entertainment of the attendees and that go beyond these purposes are most likely to be regarded as inacceptable forms of hospitality.

Paragraph 6.16 of the Blue Guide clarifies that "hospitality should be strictly limited to the main objective of the meeting and should not be offered to persons who are not healthcare professionals (e.g. partners)". Similarly, hospitality as "meetings or events held to promote medicines, provided it is strictly limited to the main purpose of the meeting or event. Hospitality should be reasonable in level".

According to Article 7(2), the rules regarding advertisements relating to medicinal products in the Regulations apply to the sponsorship of promotional meetings or scientific congresses attended by persons qualified to prescribe/supply medicinal products, including the payment of their travelling or accommodation expenses in that regard, and therefore all the restrictions in Part 14 of the Regulations apply to such sponsorship arrangements.

16. Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?

The Blue Guide implicitly accepts that health professionals may be remunerated for providing services to pharmaceutical companies (the Blue Guide names advisory boards, market research as illustrations), but insists that "particular care should be taken […] to ensure that there is no element of promotion". The services should be "clearly designed to answer legitimate business questions and the number of participants should be kept to the minimum needed for this purpose".

Clause 24 of the ABPI Code provides that it is possible to pay healthcare professionals to provide genuine consultancy or other services such as "speaking at and chairing meetings, involvement in medical/scientific

studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or travel" (ABPI Code, Clause 24.1). However, the following conditions apply:

i. The consultancy or other services must be genuine;

ii. Written contract agreed in advance specifying the nature of the services and the basis for the payment;

iii. Clear identification of a legitimate need in advance of the request; iv. Criteria for selection must be directly related to the needs, and selection must be conducted by persons qualified to verify these criteria;

v. Number of consultants limited to what is strictly necessary;

vi. Maintain records and make appropriate use of the services;

vii. the hiring of the consultant must not be an inducement to prescribe, supply, administer, recommend, buy or sell any medicine

viii. Compensation must be reasonable, reflect the fair market value;

ix. Contracts must include obligation for the consultant to declare the consultancy whenever writes or speaks on a relevant topics to the public.

ABPI Code Clause 23.2 provides that donations to "healthcare organisations, patient organisations or other organisations are only allowed if they:

• are made for the purpose of supporting healthcare, scientific research or education

• do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines

• are prospective in nature

• do not bear the name of any medicine – although they may bear the name of the company providing them.

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

Subject to the general requirements on "gifts, pecuniary advantage or benefit" – i.e. inexpensive and relevant to the practice of the activity (Article 300(1), the Regulations do not provide for any exemptions in relation to monetary donations or otherwise.

Section 6.17 Blue Guide clarifies that schemes offering "sponsorship of research posts, study visits" may be acceptable "provided that there is no element of promotion of individual products associated with them". Provision of goods and services "should not be dependent upon, or subject to, the prescription or supply of medicinal products and should not refer to them by name".

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

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.

Transfers of value to healthcare professionals in the UK are subject to the ABPI Code. Clause 28 of the ABPI Code incorporates the requirements of the European Federation of Pharmaceutical Industries ("**EFPIA**") Disclosure Code. 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.

In the UK, the ABPI has set up Disclosure UK, a searchable database, published on its website, which details transfers of value – payments and benefits in kind – made to UK Healthcare professionals ("**HCPs**") and healthcare organisations by pharmaceutical companies. The database contains details of certain payments and other benefits in kind made to individual, named HCPs annually, unless there is a legal reason why a particular HCP cannot be named.

19. When if at all with a competent authority have to get involved in authorising advertising? Is advertising on the internet (including social media) for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

Promotional material directed to a UK audience which is provided on the internet is 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 1.2 of the ABPI Code suggests that action will only 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 has developed specific guidance for consumer websites offering medicinal treatment services. The guidance sets out 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. However, any such material should not draw attention to specific POMs.

Rule 1.5.12, together with Rule 53, of the PAGB Consumer Code for Medicines provides guidance regarding all types of advertising, promotion and discussion on the Internet. The materials that are covered by the provisions include Internet materials that fall under the PAGB Medicines Advertising Codes include brand websites, social media sites (e.g. Facebook and Twitter), pay-per-click advertising, banner ads and press releases intended for Internet publication that are under the editorial control of the member company. Such material is covered by the rules set out in 1.2.1 of the same Code, and the same guidance as set out above must be followed regardless of whether the means of the advertising is on the internet or otherwise, and the copy must be sent to the PABG for approval. The following items are excluded from the Rules and as such do not need to be submitted to PAGB for approval:

Facebook posts and Twitter messages which do not mention the product, do not contain any direct or implied claims or any references to the therapeutic category

legal notices and disclaimers – these materials are not intended to promote brands and hence do not require PAGB approval. Similarly, website registration forms that do not promote brands do not require PAGB approval.

All web materials which are caught by the Rules must be submitted to PAGB in an offline format, such as a PDF or Microsoft Word document; changes must be highlighted when submitting amended copy which has been reviewed previously. The general Rules set out in 1.4.3 and 1.4.8 also apply.

There are special rules regarding the promotion of medicines to young adults and children, and websites promoting medicinal products should avoid featuring cartoons, characters and designs that are likely to be particularly appealing to children. Likely categories that might be affected are those indicated for acne and period pain. More generally, advertisers must be careful to avoid creating websites for these products that are particularly appealing to persons aged less than 16 years old. Restrictions may have to made so that only users above a particular age may have access that part of a website which deals with medicines if the website also promotes non-medicines which are promoted to children.

When advertising to young adults, special care is needed to promote a responsible and cautious approach to self-medication. Any websites incorporating games must ensure that the games either do not make reference to medicinal products, or restrict access to children over 16.

Websites are able to include advice written by a health care professional, as well as general information about active ingredients, provided that brands are not referred to within the article, and that brand advertising is kept separate.

The rules for viral advertising are the same as for all other advertising media and the aforementioned requirements for essential information apply. Equally, the rules also apply to pay-per-click advertising.

As a general overarching rule, all other requirements of the PAGB Consumer Code for Medicines also apply to web-based promotional materials over which members have editorial control.

Paragraph 6.3 of the Blue Guide provides that advertising of prescription only medicines, prohibited when targeting the general public, is allowed on websites but only those specifically directed at healthcare professionals. Where these websites are also accessible to the general public, the information directed at healthcare professionals should be clearly separated and should specify that the content of the information is intended for healthcare professionals only.

Although it is not mandatory, the MHRA considers that websites or pages of websites targeting healthcare professionals should have their access restricted to ensure that they can only be accessed by healthcare professionals.

Although it is not mandatory, the MHRA considers that websites or pages of websites targeting healthcare professionals should have their access restricted to ensure that they can only be accessed by healthcare professionals.

20. Are there any anti-bribery rules apply to communications between pharmaceutical companies and healthcare professionals or healthcare organizations?

The Bribery Act 2010 provides a legal framework to combat bribery in the public or private sectors. It includes offences covering the offering, promising or giving of an advantage, and requesting, agreeing to receive or accepting of an advantage. It is enforced by the Serious Fraud Office (SFO). The SFO has advised that this does not prevent proportionate promotional expenditure. It will not seek to prosecute unless it considers this is in the public interest, and in reaching such a decision the SFO will take into account relevant action taken by the PMCPA and the MHRA.

The Bribery Act 2010 requires organisations to implement anti-corruption policies or codes of conduct that are fit for purpose and regular anti-corruption training for its staff. A failure to implement such policies, and/or a breach of the Bribery Act 2010, is likely to result in civil and criminal liability for organisations and individuals, including agents anywhere in the world. If corruption is uncovered, and the relevant organisation responds appropriately, for example by disciplining members of staff involved, and reviewing the effectiveness of internal policies and anti-corruption training, this may help mitigate or avoid criminal liability.

21. What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?

Part 14 of the Regulations (in particular Article 300) regulates the advertising to persons “authorised to prescribe or supply medicinal products”, including any benefits (e.g. free samples, gifts or other advantages) offered to such persons.

According to Article 7, the term “advertisement”, in relation to a medicinal product, “includes anything designed to promote the prescription, supply, sale or use of that product” (Article 7(1), and specifically Article 7(2)), including:

a. “the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except where the intrinsic value of such inducements is minimal;

b. the sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products; and

c. the sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products, including the payment of their travelling and accommodation expenses in that connection.”

Paragraph 6.14 of the Blue Guide provides some guidance on the interpretation of the types of promotion which are prohibited because of their potential to adversely impact public health. It states that any “promotional activity which encourages the purchase, supply or sale of a medicinal product by PQPS ” will be caught by Article 300(1) of the Regulations if it offers a collateral benefit which does not satisfy the tests of being “inexpensive” and “relevant to the practice of medicine or pharmacy” (see section 9.1), unless it is exempt under Article 300(6). It clarifies further that any “person” promoting medicines to PQPS will be subject to Article 300(1), where the term “person” covers both corporate and unincorporated bodies as well as individuals and includes manufacturers and distributors of medicines, including wholesale dealers. Breach of

Article 300(1) is a criminal offence, as is the soliciting or accepting of any gift, benefit in kind, hospitality or sponsorship prohibited by the regulations, by a PQPS. Transfers of value to healthcare professionals in the UK are also subject to the ABPI Code. If such a transfer is made to a PQPS, to any relevant decision maker, or any company located in the UK (irrespective of where in Europe the recipients are), then such transfer is within the scope of the ABPI Code.

Where the transfer of value is either hospitality or a gift which is in some way inappropriate, that transfer may fall foul of the ABPI Code and attract sanctions. Examples include hospitality that is inappropriate and disproportional to the occasion, or a gift, pecuniary advantage, or benefit being supplied, offered, or promised in connection with the promotion or prescription of a medicine.

Possible sanctions of breaching the ABPI Code include: suspension or expulsion from the ABPI; an audit of company procedures; and the issue of a corrective statement or a public reprimand.

Similarly, the EFPIA HCP Code 2019 and the EFPIA Disclosure Code 2014 provide for its member associations to establish national procedures to receive and process complaints, determine sanctions and publish appropriate details regarding the same. If complaints are received, they should be adjudicated by the national associations of EFPIA, which should have procedures and structures for this purpose, including an appeals process. Any final decision taken will be published – and should include the company name in the case of serious/repeated breaches.

22. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

Enforcement of the rules on advertising and inducement is within the statutory powers of the MHRA who acts on behalf of Health Ministers. The Ministers, defined as the Secretary of State and Minister for Health, Social Services and Public Safety (Article 6), can either act alone or decide to act jointly (Article 278). The MHRA is also responsible for monitoring compliance with the advertising rules and will thus conduct its own review of published advertising.

Anyone can complain before the MHRA for non-compliant advertising of medicines.

Complaints can also be made before the following self-regulatory bodies (i.e. operating their own Codes of Practices):

• The Prescription Medicines Code of Practice Authority administers the ABPI Code of Practice for the pharmaceutical industry;

• The Proprietary Association of Great Britain regulates over the counter medicines and administers the Medicines Advertising Codes and the Professional Code of Practice.

• The Health Food Manufacturers' Association operates the Code of Advertising Practice on behalf of the UK specialist health product industry.

• The Office of Communications is the regulatory and competition authority for the UK communications industries responsible for programme sponsorship and product placement.

• The Advertising Standards Authority and Committees of Advertising Practice administers the UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing.

• Radio Advertising Clearance Centre is responsible for compliance of advertising on radio with the UK Code of Broadcast Advertising.

• Clearcast approves advertising for television with the UK Code of Broadcast Advertising.

• The MHRA may refer a complaint back to one of these self-regulatory bodies if it considers it is a more appropriate forum and if the alleged breach is of Articles 286 to 290, or Articles 294 to 300. If an investigation has already been conducted by one of these selfregulatory bodies the MHRA may decide not to conduct its own investigation. However, the MHRA may investigate a complaint that has been submitted to one of the self-regulatory bodies if it has not been dealt with in a satisfactory manner within a reasonable time frame.

There are two types of actions which can be brought before English courts in case of a breach of statutory duty: actions for damages based on private law (tort), and actions for enforcing the performance of a statutory duty which emanates from public law (judicial review). The former has been further classified in four categories: (a) actions for breach of statutory duty simpliciter, (b) actions based on the careless performance of a statutory duty in the absence of any other common law right of action, (c) actions based on a common law duty of care arising either from the imposition of the statutory duty or from the performance of it, and (d) misfeasance in public

office. However, the general principle is that a breach of statutory duty will not give rise to a private law cause of action unless "the statutory duty was imposed for the protection of a limited class of the public and that Parliament intended to confer on members of that class a private right of action for breach of the duty" (X (Minors) v Bedfordshire CC [1995] 2 A.C. 633 at 731).

The latter is an action that can be brought against a public body such as the MHRA where the court reviews the lawfulness of a decision in relation to the exercise of a public function. The process is designed to ensure that public bodies act in accordance with their legal obligations and do not abuse their powers.

23. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

Companies can initiate proceedings against competitors before the MHRA or any self-regulatory body. Offences are provided under Article 303(1) of the Regulations and include any contravention of any prohibition relating to advertising as well as any failure to comply with any requirement or obligation in Chapter 2 of part 14 of the Regulations.

There are no actions before English courts that can be initiated by companies against their competitors (as the breach of statutory duty would typically not cause loss to the companies and thus a private law cause of action would not be available).

24. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

The MHRA's prefers to resolve complaints quickly and informally, with companies agreeing to take voluntary action to amend their advertising, and as such prosecutions for advertising offences are rare. However, regulators do have the power to impose the penalties and sanctions set out below.

The sanctions for violating advertising and inducement rules can be criminal and/or civil. They are the same except where provided otherwise.

For any breach under Article 303(2) of the Regulations, the penalty is a fine not exceeding the statutory maximum and/or imprisonment for up to two years. For breaches under Article 303(4) which include breaches of Article 298(1) (in relation to the supply of free sample of a medicine to persons qualified to prescribe or supply medicines), Article 299(2) or (3) (relating to information which must be provided by the medical sales representative to the persons qualified to prescribe or supply medicines), and Article 300(4) (in relation to the solicitation or acceptance of gifts, pecuniary advantages, benefits or hospitality by a person qualified to prescribe or supply medicinal products), the penalty is a fine not exceeding level 5 on the standard scale.

The failure to comply with any requirement imposed by a notice given by the MHRA under Article 301 is also a criminal offence pursuant to Article 308 and the penalty is the same as for breaches under Article 303(2). However, for a breach of Article 307(2) (in relation to corrective statements concerning the incompatible advertisement), the penalty is the same as for breaches under Article 303(4).

Civil sanctions include requiring publication of a corrective statement where the Ministers have prohibited publication of advertising for breaching the rules (Article 307).

The MHRA can also require a licence holder to refrain from publishing the advertisement under investigation until a final decision is reached on the investigated violation.

25. What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?

The various procedures operate independently from each other and are not dependent on the outcome of other reviews by other authorities or courts. As mentioned above, there are limited actions that can be brought before English courts in relation to breaches of statutory duties. Judicial reviews are available but only against public bodies (i.e. created by statute).

26. Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.

In 2021/2022, collaboration between the MHRA's enforcement group and the online marketplace resulted in the removal of 100 illicit adverts for unlicensed

medicines.

The overall number of complaints received by the MHRA were down compared to 2020 (277 in 2020 versus 144 in 2021).

The number of decisions was also down from 2021 levels (18 in 2022 compared to 24 in 2021). However, the number appears to be rising for 2023, as there have been 19 decisions this year so far up to July (the most recent data). There continues to be a focus on self-regulation, albeit with significant cooperation with regulatory bodies such as the ASA or PMCPA.

Two recent cases include the following:

In July 2023, following MHRA action, a number of companies have amended their advertising to ensure that the POM 'Kenalog' is not promoted to the public for the treatment of hayfever. As stated above, the promotion of any POM to the general public is prohibited in the UK. Furthermore, Kenalog is not a licensed treatment for hayfever.

In February 2023, the MHRA upheld a complaint that an advertisement for Lemsip Max All in One appearing on a poster on the London Underground suggested to consumers that the medicine could be taken to prevent a cold, which broadened the potential use of the product beyond the appropriate scope and was therefore in breach of regulation 280(1), 280(2) and 280(3) HMR 2012.

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