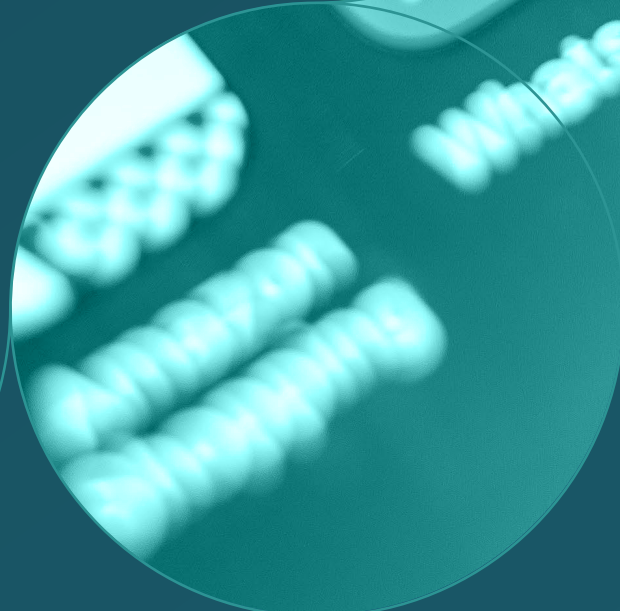


PMCPA
Social Media
Guidance 2023



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PMCPA Social Media Guidance 2023

In the UK, the control of medicines advertising is based on the long established system of self-regulation supported by the statutory role of the Medicines and Healthcare products Regulatory Agency (MHRA). The Association of the British Pharmaceutical Industry (ABPI) Code of Practice (ABPI Code), administered by the Prescription Medicines Code of Practice Authority (PMCPA), is the self-regulatory system covering prescription medicines. The ABPI Code reflects and extends beyond UK law. A Memorandum of Understanding setting out the arrangements for the regulation of the promotion of medicines for prescribing was agreed between the PMCPA, the ABPI and the MHRA.

The PMCPA cannot approve any materials or activities, it can only give informal advice based on its interpretation of the ABPI Code. In the event of a complaint being received about a matter upon which advice had been sought, it would be considered in the usual way; the Code of Practice Appeal Board would make the final decision if a case went to appeal. In the event of a complaint each case would be judged on its merits.

The ABPI Code covers the promotion of medicines for prescribing to both UK health professionals and other relevant decision makers. In addition, it sets standards for the provision of information about prescription only medicines to the public. It does not apply to the promotion of over-the-counter (OTC) medicines to members of the health professions when the object of that promotion is to encourage their purchase by members of the public. Thus, for example, where the advertisement is designed to encourage health professionals to prescribe the medicine, then it comes within the scope of the ABPI Code. The promotion of over-the-counter (OTC) medicines to the public for self-medication purposes is covered by the Consumer Code of the Proprietary Association of Great Britain (PAGB).

It is a condition of membership of the ABPI to abide by the Code in both the spirit and the letter. The Code applies to both members and affiliate members of the ABPI. Companies which are not members of the ABPI may give their formal agreement to abide by the Code and accept the jurisdiction of the PMCPA. The Code covers the industry's activities only. However, those interacting with industry as individuals or organisations also have a responsibility to ensure that their interactions comply with relevant legal requirements and are asked to follow the Code where relevant and not make requests that are not in accordance with the Code.

This guidance has been developed by the PMCPA following a project set up involving various stakeholders including the MHRA, the ABPI and pharmaceutical company representatives, which identified the areas where pharmaceutical companies required further guidance, and building on the extensive work the PMCPA had already done on this topic previously. This guidance reflects the relevant UK legal requirements as well as the codes of practice and guidance and advice from the European Federation of Pharmaceutical Industries and Associations (EFPIA), the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), and the MHRA. It also outlines PMCPA views based on available case precedent.

As with any guidance document, it does not replace the need for pharmaceutical companies, including their employees, partners, third parties and the like to follow the ABPI Code and all other applicable codes, laws and regulations to which they are subject. It also does not identify all the requirements that must be followed for each activity, as they may vary significantly depending on the nature of the activity. **A list of relevant legislation, Codes and Guidelines are listed on page 65 of the 2021 ABPI Code.**

Introduction

Pharmaceutical companies want to, and indeed can use social media. However, unlike certain other industries, which can legally promote their products to all, pharmaceutical companies are prohibited from promoting prescription only medicines (POMs) to the public and from promoting a medicine prior to the grant of the marketing authorisation which permits its sale or supply. Therefore, pharmaceutical companies need to identify ways of utilising social media whilst complying with these restrictions. This guidance focuses on what pharmaceutical companies should be aware of when considering activities on digital

channels such as social media. A social media channel is only a platform for communicating and consuming information. Laws and regulations applicable to other platforms and media also apply to digital media including social media. The content, target audience and use of the platform are relevant factors to determine applicable rules, not the media as such. Pharmaceutical companies should always bear in mind the impact the information might have and the overall impression created by their communications, activities and materials.

What is Social Media?

Social media is a term used to describe websites and applications that enable users to create and share content and to interact with one another in social networks, for example:



Twitter



LinkedIn



Facebook



Instagram



TikTok



YouTube

Social Media allows users to communicate and interact/engage in real time including posting, liking, commenting and sharing. In general, social media platforms are digital channels that are used to reach or interact with as many individuals as possible and are considered to be aimed at the public.

However, some social media platforms can also be used as a closed channel for a specific audience where verification/disclosure of the audience status or credentials is possible and can be required before providing access. For example, currently some social media networks such as LinkedIn allow closed user groups where the user invites individuals to join a group which they can restrict to a specific audience eg health professionals. There might be a limit to the number of individuals who can be invited, depending on the platform used. Platforms such as LinkedIn currently have functionality to target materials to health professionals by job title, education and specialism.

The target audience of the closed channel/group or activity should be clearly identified.

A pharmaceutical company may choose to have one corporate account or separate accounts dedicated to specific activities or stakeholder groups. Pharmaceutical companies should consider how each activity is restricted and tailored to the needs of the intended audience.

Due to UK legal requirements and the open and transitory nature of social media channels, pharmaceutical companies should consider carefully before engaging in and facilitating discussions about medicinal products or treatment options on these channels.

Pharmaceutical companies should be aware of the current terms and conditions for the social media channels it uses and engages with, and General Data Protection Regulation (GDPR) requirements.

Pharmaceutical companies should establish procedures to review and monitor their activities,

content, and materials on social media to ensure compliance with relevant codes and applicable laws including monitoring of adverse events. Annex II Principles for the use of digital channels of the EFPIA Code states that for digital channels owned by the pharmaceutical company, processes should be established to monitor, moderate and/or delete any inappropriate comments in a timely manner to the extent permitted by the data protection regulations and applicable laws and codes. Pharmaceutical companies might need to have similar processes when using digital channels owned by other companies or organisations.

Pharmaceutical companies are encouraged to have social media community guidelines in place. These guidelines should set the expectations and boundaries to clarify what behaviour is expected

online. They are important to help the company protect its community as well as the company.

Attention should also be given to the Advertising Standards Authority UK Code of Non-broadcast Advertising and Direct & Promotional Marketing (CAP Code) which sets out the rules for non-broadcast advertisements, sales promotion and direct marketing communications.

A Glossary of Social Media terms is available in Appendix A

This guidance recognises that the definition and uses of social media are continually evolving. It is therefore important to understand the general wider principles which apply and that are set out within this guidance document.

Principles for Social Media Activities.

Key questions to consider before carrying out any social media activity:

- What is the objective of the activity?
- What content will be made available?
 - Is the content promotional or non-promotional?
 - Is the content related to medicines?
 - Does the medicine have a marketing authorisation/is the indication covered by the marketing authorisation?
 - Is the content related to educational information for the public?
 - What information is linked to and therefore forms part of the content?
- Who is the audience (for example, public, health professionals, media, investors) and is the content suitable and appropriately signposted for that audience?
- Are there licence variations between Great Britain (GB) and Northern Ireland (NI)?
- Has access been limited to the appropriate intended audience? Is interaction with the social media activity limited or controlled, and if not how does this affect the risk of the activity?
- Is the audience expected to respond or participate in discussion?
- Is the role of the pharmaceutical company clear?
- How is the content reviewed, approved and maintained?
- What are the arrangements for pharmacovigilance obligations?
- Why could it not be considered as promotion to the public?
- Is it in line with company guidance, is the company guidance clear and consistent with all applicable codes, laws and regulations?

Transparency

Pharmaceutical companies should always be transparent about the communications, activities and materials they produce, publish, sponsor, fund, or support on social media. Whenever a pharmaceutical company or a third party

acting on its behalf publishes content on social media, it should clearly and prominently state the involvement of the pharmaceutical company and users should be aware of such involvement at the outset.

Responsibility

With regards to the ABPI Code, a pharmaceutical company is responsible for all material disseminated/activities carried out by it on any social media channel that comes within the scope of the ABPI Code including by a third party acting on its behalf even if that third party acts beyond the scope of its contract and potentially material/activities sponsored by it.

Contracts with third parties should deal comprehensively with ownership and control including use of and potential withdrawal of materials both during and after the contracted period. This includes ensuring individuals such as contracted speakers/influencers and the like are aware of the requirements of the ABPI Code, particularly in relation to social media and the prohibition on advertising POMs to the public. Pharmaceutical companies are strongly advised to preview social media content from their contracted parties in relation to their contracted activities and of course are responsible for certification of these posts as required by the ABPI Code.

Pharmaceutical companies may also have responsibilities when interacting on social media accounts owned by other companies or organisations eg engaging with posts on those accounts including for example 'liking' or commenting on them.

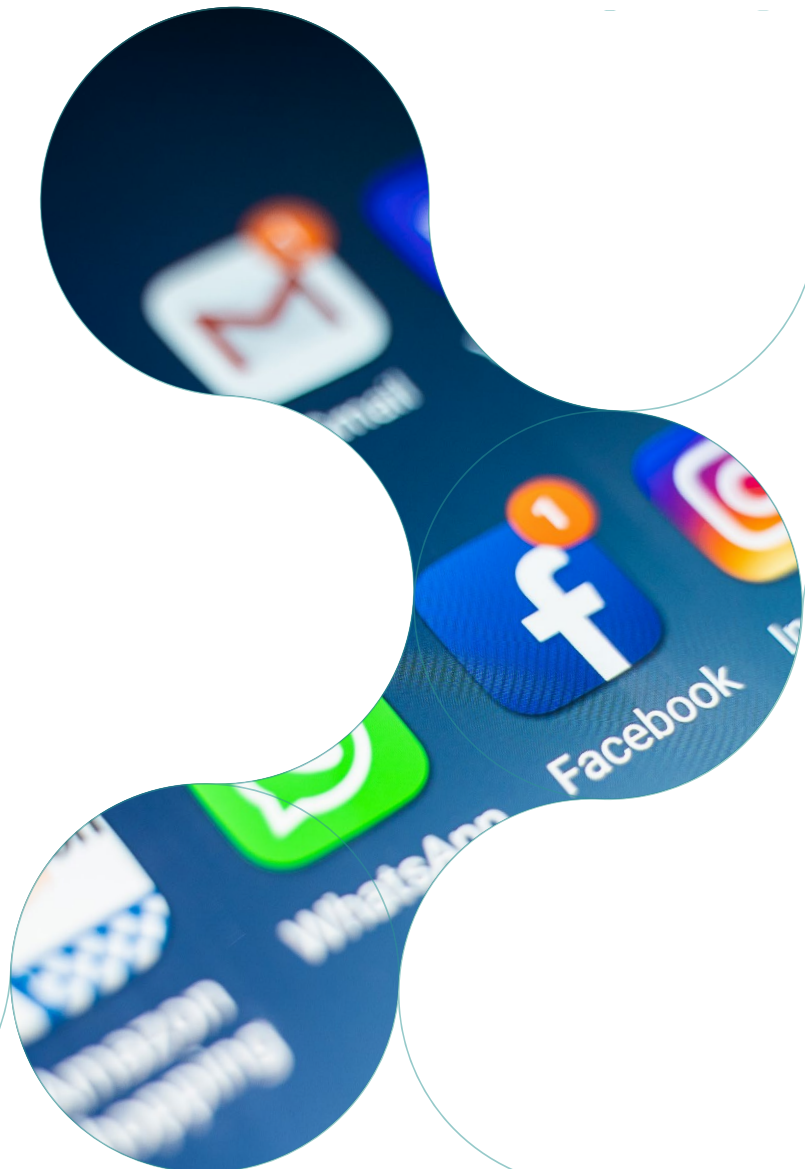
The personal use of social media by pharmaceutical company employees has the potential to overlap with their professional responsibilities. As such employees should act with due caution when using all social media platforms, including LinkedIn, to discuss or highlight issues which relate to their professional role or the commercial/research interests of their company.

An individual's personal activity on social media such as posting, liking, sharing will, in the first instance be visible to his/her connections and will potentially be visible to others outside his/her network depending on the individual's security settings. Pharmaceutical company employees should assume that such activity would, therefore, potentially be visible to both those who are health professionals or other relevant decision makers and those who are members of the public.

Pharmaceutical companies may be held responsible for engagement with, or dissemination of, information by company employees who do so via their personal social

media channels including, (a) if the employee can reasonably be perceived as representing the company, and/or (b) if the employee is instructed, approved, or facilitated by the company to do so. Pharmaceutical companies should ensure that they have appropriate policies in place and relevant employees receive regular training appropriate to their role, for responsible conduct on social media.

If an employee's personal use of social media was found to be in scope of the ABPI Code, the company would be held responsible. Pharmaceutical companies should assume that the ABPI Code would apply to all work-related, personal social media posts, for example, LinkedIn or Instagram posts/activity by their employees unless, for very clear reasons, it could be shown otherwise.



When do posts placed on social media platforms outside the UK fall within the scope of the ABPI Code?

This is set out under Clause 1.2 of the 2021 ABPI Code. There has to be a UK nexus such as the activity is carried out by the UK company or with its authority or an affiliate of a UK company or with its authority and makes specific reference to the availability or use of the medicine in the UK. If a UK-based or UK company employee interacts/engages with a post such as 'liking'

the post, which would typically result in it being disseminated to their connections/followers or appearing in the employee's posts or social news feed, then it would likely be subject to the ABPI Code.

The content and intended geographical audience may be relevant when determining whether there is a UK nexus.

It is an established principle under the ABPI Code that UK pharmaceutical companies are responsible for the activities of overseas affiliates where those activities come within the scope of the ABPI Code.

There are no exceptions to the applicability of the ABPI Code depending on which part of the business, ie finance, medical or commercial has issued or engaged/interacted with a post.

Overarching Considerations

There are important overarching considerations for all social media activity which have been outlined below for each category, but there might be specific considerations that are not covered by the general comments below.

Pharmacovigilance

Pharmaceutical companies should implement policies and/or procedures on social media platforms to ensure they meet their pharmacovigilance responsibilities including the obligation to record and report any adverse effects that are discussed about their medicinal products. Such policies and procedures should include information about how adverse events can be reported.

The ABPI Code has only limited requirements in this regard, in that promotion has to include a reference to reporting adverse events (Clause 12.9) as does certain information for patients (Clause 26.4) and the public in relation to campaigns approved by health ministers (Clause 26.1 supplementary information). In addition, pharmaceutical companies must ensure that all personnel (and others retained by way of contract) are fully conversant with pharmacovigilance requirements relevant to

their work and this must be documented (Clause 9.2). The current position in the UK is that if a pharmaceutical company (or an individual or third party on its behalf) becomes aware of an adverse event associated with one of its products then certain information has to be collected and reported to the MHRA. The MHRA advice is that pharmaceutical companies should signpost social media users to how they can officially report adverse events (website address) in relation to posts which contain safety information. Further information can be obtained from the MHRA.

It is recommended that comments underneath advertising/communications and direct messages to company owned or sponsored social media accounts are monitored for pharmacovigilance; alternatively, they can be restricted on certain social media channels.



General applicability of laws, regulations and codes

Clauses 1-10 of the ABPI Code set out the overarching requirements that need to be considered in all instances. A good starting point when deciding which other clauses within the ABPI Code are relevant is to identify the audience for the communication and refer to the applicable sections of the ABPI Code.

Clause 1.17 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'.

The EFPIA Principles for the use of digital channels states that a company owning the social media page or site is responsible for the content, for example, any mention of a POM is likely to be considered promotion of that medicine to the public and is prohibited.

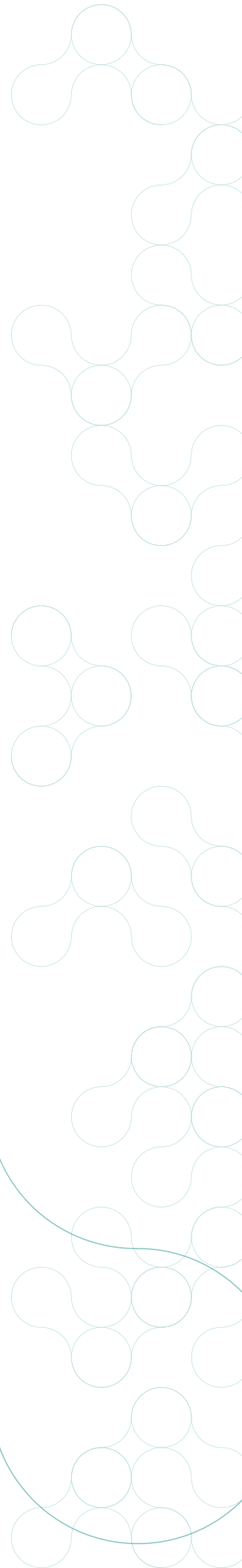
In addition, the PMCPA informal advice is that, in general, the product name (brand or generic), particularly if alongside its indication, is likely to be seen as promotional and it is advisable for pharmaceutical companies to take this approach and then show that the material is not promotional. It is also an accepted principle under the ABPI Code that depending on the context, a product could be promoted with either

the product name, indication, or even without its name ever being mentioned.

Annex II Principles for the use of digital channels of the EFPIA Code states that the use of social media directed to the public to alert health professionals about the publication of a study on a medicinal product is also likely to be considered promotion of that medicinal product and is therefore prohibited.

It has generally been the case that there might be a difference between proactive and reactive pharmaceutical company activities. Examples are set out in relation to information to the public in the supplementary information to Clause 26.2 of the ABPI Code. It is important to note that activity conducted on social media that could potentially alert one's connections to an activity or material might be considered proactive dissemination of material. The proactive dissemination of material, including the name and/or indication of a medicine on social media, is likely to be considered promotion of that medicine whereas the provision of the same information reactively or as reference information which requires one to search for it is less likely to be considered promotion of that medicine. Such information, however, must not be presented in such a way as to be promotional in nature.

Promoting a POM to the public is prohibited by UK law (as well as by European law), as is the advertising of a medicine which has not received a marketing authorisation. Use of social media platforms must not constitute promotion of POMs to the public or promotion of a medicine prior to the grant of its marketing authorisation.





The ABPI Code distinguishes between the public and patients prescribed a particular medicine in certain instances but there is no such distinction in UK law.

Clauses 3.1 and 11.1 of the ABPI Code prohibit the promotion of a medicine prior to the grant of its marketing authorisation. Promotion prior to the grant of a marketing authorisation is given as an example of an activity likely to be in breach of Clause 2 of the ABPI Code. This requires that activities or materials must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry. A ruling of a breach of Clause 2 is seen as a sign of particular censure.

Clauses 3.2 and 26.1 prohibit the promotion of Prescription Only Medicines to the public. This prohibition does not apply to vaccination and other campaigns carried out by pharmaceutical companies and approved by the health ministers which is an exceptional situation.

Clause 11.2 also requires that promotion must be in accordance with the marketing authorisation and not be inconsistent with the summary of product characteristics (SPC).

The proactive provision of information by a pharmaceutical company about the unauthorised use of a medicine (including 'off-label prescribing') is very likely to be seen as promotion and in breach of the ABPI Code. There are certain exemptions set out in the supplementary information to Clauses 3.1 and 11.1 of the ABPI Code.

Whilst the term 'investigational' or 'during the development of a medicine' is not defined in the ABPI Code, the PMCPA query whether a product, for which a marketing authorisation has been applied for anywhere in the world or which is expected to be available within a short timeframe, could be considered to be an 'investigational molecule' or still in development. In the PMCPA's view, audiences are likely to view such medicines as pre-licence products rather than investigational or medicines in development. UK legal requirements only refer to products with or without a marketing authorisation with no further distinction.

Particular attention is drawn to the overarching requirement for UK activity to comply with Part 14 (Advertising) of the Human Medicines Regulations 2012. The MHRA acts on behalf of Health Ministers to oversee this area of law to protect public health and is obliged to consider any complaints made to it about the advertising of medicines. The MHRA can refer complaints to the PMCPA as appropriate. Complaints are investigated by the MHRA on their own merits looking at the facts of the case and whether the content of concern is considered an advertisement for a medicinal product under the Regulations – ie something that is designed to promote its prescription, supply, sale or consumption. It is an offence for any person to be in breach of the Regulations. (For the Regulations definition of "Advertisement" and 'medicinal product' see the Human Medicines Regulations 2012 as referred to on Page 19).

Guidance

Please note that generally the activities below consider the public use of social media as opposed to closed private forums or groups where access to content is restricted.

Links

Any material associated with a post, for example, a link within a LinkedIn post, would normally be regarded as being part of that post. Pharmaceutical companies should be confident about the choice of linked information/websites and that these do not promote POMs to the public or contain otherwise inappropriate content. Due diligence needs to be applied in assessing the appropriateness of content being linked to, in a manner similar to that which is applied when directing readers to independent organisation's websites in promotional or other materials.

Links in company posts should:

- be clear and the name of the link should be appropriate.
- clearly state whether the link is to the pharmaceutical company material/website or other non-company material/website.

Linked material:

- should be clear regarding the intended audience and if the pharmaceutical company had any involvement in it.
- can provide links to other information for the intended audience.
- should include instructions for those who are not the intended audience in order to direct them to relevant information where required.

Mentioning other accounts

Most social media platforms enable other accounts to be mentioned in posts which usually sends them a notification about the post. (See Tagging below)

Pharmaceutical companies can mention different stakeholders in their posts, including health professionals, healthcare organisations and patient organisations. Their permission might not be required to mention them, but care must be taken to ensure that stakeholders are mentioned respectfully and only brought into relevant discussions.

Hashtags and Tagging

Tagging

Many social media platforms enable users to tag posts to facilitate browsing and searching.

Pharmaceutical companies should be cautious about the effect of tagging others and thus directing readers to the associated social media account. If a pharmaceutical company/company employee linked to a health professional's social media account that contained promotional content for the company's medicine this would likely be in breach of Clause 26.1 of the Code if there was evidence to show that the promotional content appeared on the linked account at the point the linkage was made.

Individuals have control over whether or not to tag others in their posts. In that regard, pharmaceutical companies/employees that include tags as part of their posts and therefore direct readers to other accounts, need to be satisfied that the content on those accounts are appropriate as far as the ABPI Code is concerned. If that were not the case, then pharmaceutical companies/employees would be able to direct readers to independent profiles and their contents as a means of circumventing the ABPI Code.

Whether a linked account/tag came within the scope of the ABPI Code has to be decided on a case-by-case basis, taking into account all of the circumstances including, among other things, the content of the linked/tagged account and the chronology of the link.

Hashtags

A hashtag is a word or key phrase preceded by a hash symbol #. Hashtags are used within social media posts to help those who may be interested in the topic to find it. Clicking on a hashtag would take readers to the hashtag's feed where they could see content posted which related to the hashtag topic and view all posts which mentioned that hashtag.

Caution must be taken by pharmaceutical companies to ensure that appropriate hashtags which are relevant to the content are chosen. Choosing a hashtag that contained a claim for a prescription only medicine would likely constitute promotion. An indication or therapy area eg #obesity might constitute promotion of a product if it was used in combination with other language which could identify a specific product. Particular care should be taken where the company's product, even though not named, is the only medicine available for the disease or symptoms in question. Pharmaceutical companies should give consideration to the fact that hashtags are often not owned or controlled by the company and an individual hashtag could therefore be used for multiple different purposes at the same time.

➤ **Example:** See Cases AUTH/3431/11/20 and AUTH/3441/11/20

Responding to Misinformation/ Correcting inaccuracies

Responding to misinformation or inaccuracies about POMs published on social media is a difficult area and is a question of policy for a company. Simply adding a cross-reference to the regulatory documents such as SPCs and package leaflets either on a company site, or to the Electronic Medicines Compendium (eMC), might not be considered to be unreasonable. Cross-referring to a particular section of such documents might be less acceptable as an element of judgement had been introduced rather than the simple 'more information is available in the SPC or PIL'.

A pharmaceutical company could refer readers of the particular misinformation to its own reference information (as defined in the supplementary information to Clause 26.2 of the ABPI Code)

about the medicine by means of a link to an appropriate landing page.. Clearly all the reference information needs to comply with the ABPI Code. (NOTE: This is a limited additional use for reference information – a proactive use rather than a reactive use and is limited to correcting specific published misinformation or inaccuracies about POMs published on social media and not in relation to general misinformation a company is aware of). Such information, however, must not be presented in such a way as to be promotional in nature.

Correction of material might lead to more challenges as it would be beholden on the pharmaceutical company to ensure that everything was correct – otherwise why correct some inaccuracies but not all?

Signposting vs Posting/ Sharing/ Re-sharing

It is important to differentiate between disseminating information directly through posting and sharing/re-sharing content and signposting to information. The difference is critical to engaging with stakeholders in social media compliantly.

Signposting

Signposting points to information while clarifying who the information is for and the nature of the information and requires confirmation of the audience prior to accessing it. Depending on the circumstances this might be self-validation by the individuals (for example accessing a product website following confirmation by the individual that he/she is a health professional) or validation of the individuals by the pharmaceutical company (for example upon joining a closed user group).

Consideration must be given to ensure that signposting is used when the information is intended only for a specified stakeholder group to alert readers as to who is the intended audience. The information on the 'signpost' must be sufficient to enable the viewer to determine whether the information is relevant to them and to choose to find out more but should not constitute the promotion of a POM to the public. Neither should it constitute the promotion of an unlicensed medicine or an unlicensed indication for a licensed medicine. It is likely that splitting key information across multiple posts will not be appropriate.

For example, signposting can be used to invite health professionals to register for a promotional meeting indicating that the meeting is for UK

health professionals only and will include product promotion. The information provided in the signpost must not directly or indirectly promote a POM. Following validation, further information about the meeting can be provided. More formal validation for meeting registration/attendance might be required to ensure only appropriate attendees attend the meeting itself. The key point being that no product promotion is seen until after validation and only appropriate attendees register for/can attend the meeting.

It is important that the target audience is very clear at all times including on the original social media post, the content of the original post is appropriate for the public, and that the audience is required to self-validate before accessing the material which is housed on the company's or another website in a section tailored to the relevant audience (see also Product and Pipeline Milestones below).

Posting information is the proactive provision of information directly on a social media platform through the creation of content.

Sharing/Re-sharing

Most social media platforms enable users to engage in some way/interact with content on other accounts and such engagement/interaction might result in the further dissemination (sharing/re-sharing) of the content. Care must be taken when sharing/resharing content to ensure that the post and any linked content is in line with the ABPI Code and approved/certified if necessary. The account owner is responsible for the content they choose to share/reshare to their followers. Furthermore, it is important to understand exactly how each platform currently works as sometimes simply engaging with a post, for example, 'liking' a post on LinkedIn or retweeting on twitter can alert one's connections to the content; both of which are considered to be a type of 'sharing/re-sharing'.

Content posted/shared/re-shared by pharmaceutical companies that relates to products or diseases should be examined to confirm compliance with the ABPI Code and where applicable certified in advance (eg educational material for the public).

Corporate News and Announcements

Pharmaceutical companies can post or share/disseminate corporate company news (not product related) on social media. The news that is shared/disseminated must be appropriate for the public. News can include, for example, new executive appointments, corporate partnerships and acquisitions, employee recognition, and company awards. This category does not include signposting to information about products or pipeline assets, including clinical research (see below). Such shared/disseminated content should not directly or indirectly mention products.

Professional Profiles and Job Advertising

Social media platforms, such as LinkedIn, are widely used to share professional profiles publicly to show an individual's previous work experience and current role. These professional profiles can be used by employers to find candidates and by job seekers to apply for jobs.

Job titles and descriptions in both employee profiles and company job advertisements should avoid mentioning POMs, particularly alongside the product indication, therapy area, or key product benefits, as this is likely to constitute promotion. This is especially important on platforms where updates to the profile or job advertisement might be sent to others as notifications. A poorly worded job title that was

proactively distributed to many people, is likely to be considered to be promotion of a POM to the public. It might, however, be permissible to include in an appropriate and proportionate way, brief details with regard to product names and/or therapy areas worked in within the more detailed 'Experience' section of a professional profile if it was relevant to prospective employers and if it would require an individual to actively search for it and involve additional clicks and/or scrolling by the reader to view the information.

➤ **Example:** See Cases AUTH/3287/12/19, AUTH/3410/10/20 and AUTH/3476/2/21

Disease Awareness for the Public

Disease Awareness can be conducted by a pharmaceutical company via social media provided that the purpose is to increase awareness of a disease or diseases and to provide health educational information on that disease and its management. It can encourage members of the public to visit their health professional to seek treatment while in no way promoting the use of a particular medicinal product. The use of brand or non-proprietary names and/or restricting the range of treatments described in the campaign might be likely to lead to the use of a specific medicine. Particular care must be taken where the company's product, even though not named, is the only medicine relevant to the disease or symptoms in question. Any websites or other materials linked to a social media post to promote disease awareness must also be non-promotional.

Attention is drawn to the MHRA Blue Guide Appendix 7, Disease Awareness Campaign Guidelines.

Care must also be taken to bear in mind the considerations for certification of educational material for patients or the public which relate to diseases or medicines, even if such material is generated by a non-UK affiliate or third party (such as a patient organisation) and disseminated (eg liked/shared) by UK employees.

➤ **Example of what might be acceptable:** Paid display advertising on Facebook or Twitter about a disease awareness campaign directing people to a dedicated disease-orientated Facebook page or website for further information.

Patient Support

Pharmaceutical companies can use social media to host information for patients who have been prescribed a specific POM such as videos hosted in secured sections on social media platforms like YouTube. The target audience should be clearly identified and the content appropriate for that audience.

➤ **Example of what might be acceptable:** Videos about how to take a medicine correctly, developed by a company and hosted on a section of a social media platform such as YouTube with a unique URL which can be shared with patients who have been prescribed the medicine and clearly identifies the target audience as those who have been prescribed the medicine.



Meetings Advertisements

Pharmaceutical companies can use social media to both signpost activities, such as webinars, and also run the activity itself. Care must be taken to ensure promotional activities are not disguised and access is limited to health professionals where required. Please refer to the section on signposting above for more information.

➤ **Example of what might be acceptable:**
A tweet shared via a corporate Twitter account about a webinar that is linked to a webpage provided for UK health professionals to register for the event, and with only health professionals able to access the event and event content. The tweet should be signposted as for UK health professionals and if the event will discuss the company's medicines it should state this without naming any such medicines either directly or indirectly.

Product and Pipeline Milestones

Typically press releases and information for investors and potential investors and press releases for journalists have been sent directly to these audiences and provided in a publicly accessible section of a pharmaceutical company's corporate website that is clearly labelled with the intended audience identified.

The supplementary information to Clause 26.2 of the ABPI Code Financial Information states that information made available in order to inform shareholders, the Stock Exchange and the like by way of annual reports and announcements etc may relate to both existing medicines and those not yet marketed. Such information must be non-promotional, accurate, presented in a factual and balanced way and not misleading, taking into account the information needs of the target audience. Business press releases should identify the business importance of the information and should only be aimed at the intended financial and investment audience.

Increasingly pharmaceutical companies wish to use social media to inform investors or prospective investors and/or appropriate journalists of newsworthy information as well as significant changes affecting company investor outlook. Using social media channels to communicate this information is complex as by their nature social media channels are open to a broad audience, beyond the intended audience for the post itself.

Pharmaceutical companies should note there is a difference between making a press release/information available only to investors or to the relevant press, to be published or not, and linking to it on a social media platform open to the wider public where it may be read by a broader than intended audience.

Pharmaceutical companies should consider the following safeguards when considering such posts on social media:

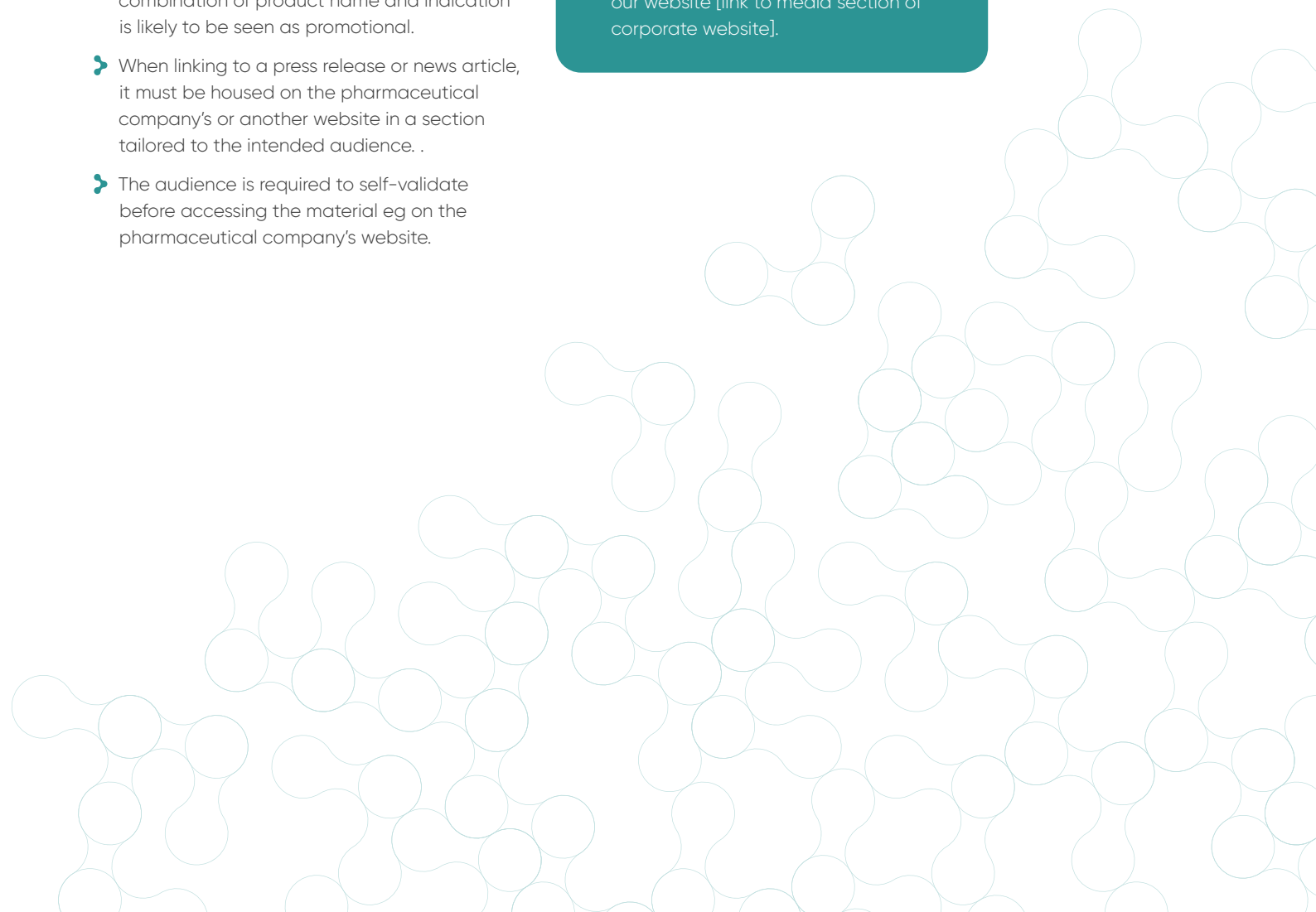
- Assessment of whether the information within the post/press release being signposted to is newsworthy bearing in mind the intended audience.
- The material should be tailored to the intended audience.
- Clear signposting of the intended audience the post is targeted at.
- Any information provided must be factual, balanced and must not encourage members of the public to ask their doctors or other prescribers to prescribe a specific prescription only medicine. It must not constitute the advertising of prescription only medicines to the public. Neither must it constitute the promotion of an unlicensed medicine or indication.
- The EFPIA Code of practice Principles for the use of digital channels states, inter alia, any mention of a POM is likely to be considered promotion of that medicine to the public and is prohibited and the PMCPA informal advice is that, in general, the combination of product name and indication is likely to be seen as promotional.
- When linking to a press release or news article, it must be housed on the pharmaceutical company's or another website in a section tailored to the intended audience. .
- The audience is required to self-validate before accessing the material eg on the pharmaceutical company's website.

Despite the safeguards above, pharmaceutical companies should consider using dedicated closed groups for journalists and investors to share such information. The account, the posts, the website pages and the linked press releases must all make the intended audience clear. Care must be taken as excessive social media activity might constitute promotion.

Attention is drawn to Chapter 7 of the Blue Guide and Blue Guide Appendix: Reporting to the public on medicines: Advice for journalists and patient organisations produced by the MHRA.

➤ **Example of what might be acceptable:**

An informative statement shared via a corporate public LinkedIn account which is linked to a press release within the media section on the corporate website about recently published results for an unlicensed medicine. The statement on LinkedIn should not mention product name or study name, but should clearly signpost the intended audience, for example, 'For Investors' or 'For Medical Media' and might state 'new press release regarding recently published data in Oncology is available on our website [[link to media section of corporate website](#)].



Working with Social Media Influencers

Online influencers and digital opinion leaders may be experts on specific issues or may be media figures within an area or sector. Some examples of online influencers include, but are not limited to, health professionals, patients, patient advocates, celebrities or TV personalities.

Because of their expertise in reaching people via social media, online influencers and digital opinion leaders may be engaged as consultants and advisors for services, including creation and co-creation and posting of digital content.

Transparency is critical and the relationship between the pharmaceutical company and the influencer must be made clear at the outset. Care must be taken to ensure that the experts who are selected have the appropriate expertise, are aware of the pharmaceutical company's responsibilities and all other required obligations are followed, such as contracts being put in place and educational material for the public being certified in advance.

Engaging with online influencers requires careful consideration, including assessment of the risks of undue influence on health professionals or the public, or risks that such digital content could be perceived as improper promotion of medicines. Pharmaceutical companies should evaluate the context of each engagement and ensure that their interactions comply with the ABPI Code and applicable laws and regulations. As with any consultant who provides a service to a company that is within the scope of the ABPI Code, the company might be held responsible under the ABPI Code for the influencer's actions even if he/she acts contrary to his/her written agreement/briefing.

Attention should also be given to the Advertising Standards Authority UK Code of Non-broadcast Advertising and Direct & Promotional Marketing (CAP Code) and its guidance in this regard.

➤ Example of what might be acceptable:

Using a social media influencer who is living with the condition as a consultant to support a disease awareness campaign and share disease information to counteract misinformation.

Promotion to Health Professionals and Other Relevant Decision Makers (ORDMs)

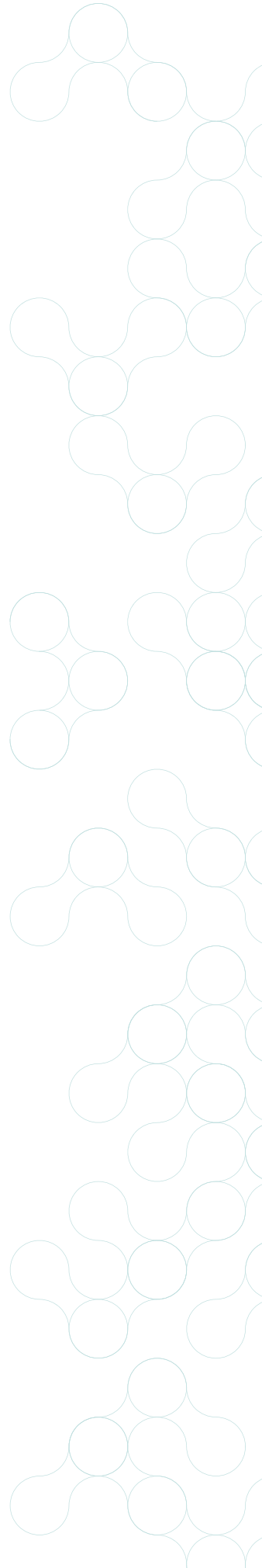
Paid for promotion (advertising) has traditionally been done through, for example, medical and scientific journals which are now online with advertisements appearing on scientific journal websites. A similar approach might be taken to purchase paid social media display advertising. Currently social media platforms such as LinkedIn allow for the creation of restricted audience groups such as health professionals and currently have functionality to target advertising material to health professionals by job title, education and specialism. Care must be taken as POMs must not be advertised to the public so promotional activities must be carefully targeted to relevant health professionals only.

The MHRA's view is that due to UK legal requirements and the open and transitory nature of these social media platforms, pharmaceutical companies should consider carefully before engaging in and facilitating discussions about medicinal products on these channels.

It is important to consider the reach of the channel/platform and the ability for the company to control who can and cannot receive the information being provided. Pharmaceutical companies should consider what controls could be put in place to restrict the sharing of such promotion on social media platforms to avoid content being re-shared with other audiences, such as members of the public.

It is also important that pharmaceutical company involvement is clear from the outset and all other obligatory requirements in relation to promotion to health professionals are met, such as the provision of prescribing information, the adverse event reporting statement and obtaining prior permission from the health professionals to receive promotional material in this way as required by Clause 15.5.

Pharmaceutical companies should also bear in mind Clause 5.6 of the ABPI Code which states that material should only be provided or made available to those groups of people whose need for or interest in it can reasonably be assumed and the material should be tailored to the audience to whom it is directed.



Clinical Trial Recruitment

Recruiting participants for clinical trials is complex and can be challenging so it may be beneficial to use social media to advertise the need for participants and invite them to look into joining a trial. Pharmaceutical companies must ensure that the advertising is carefully targeted at appropriate individuals who it can reasonably be assumed fulfil the demographics/criteria for the trial and can then be screened. Any information shared must not raise unfounded hopes of entry into the trial or successful treatment outcomes.

Care needs to be taken, particularly when in relation to a new medicine or extension of indications under investigation for a licensed product. Pharmaceutical companies must avoid referring to specific products and are encouraged to include a description that supports appropriate people/patients in the disease area to find out more information.

When social media is used in relation to recruitment for clinical trials, pharmaceutical companies need to consider all other applicable codes, laws and regulations in this regard including consideration for reviewing any comments or direct messages for adverse events or issues reported by trial participants and the requirements of the Health Research Authority (HRA).

➤ Example of what might be acceptable:

Paid Facebook advertisements targeting a specific demographic to invite patients with a condition to apply to participate in a clinical trial. A link should be provided to relevant information from the NHS/body organising/conducting the trial.



Appendix A

Glossary of social media terms

Social Media Engagement and Followers

Comments

It is usually possible to publicly comment on, or reply to, posts shared in social media. This enables viewers to discuss, engage with and react to shared content. Most platforms enable comments by default for anyone who views the post, however, in certain circumstances, it is possible to prevent viewers from commenting by turning this functionality off.

Followers

One of the main ways to engage with different people and organisations on social media (or on social media platforms) is to follow their accounts and to increase the followers of your accounts. This enables you to see the content of the accounts you follow in your content feed and the content you share to be seen by your followers in their feeds. Followers (Twitter, Instagram and TikTok) can also be called friends (Facebook), connections (LinkedIn) or subscribers (YouTube).

Social Media Influencer(s)

A social media influencer is a person or a brand with a notable following in a particular area and the power to affect the views/decisions of their audience. Some examples of online influencers and digital opinion leaders include, but are not limited to, health professionals, patients, patient advocates, celebrities or TV personalities.

Profiles

All social media platforms enable an account owner, whether an individual or a company, to create a social profile that can include information about the account owner and the purpose of the account. Profiles often include images, logos and videos which enable a company to use imagery and interactive elements so followers can quickly understand who owns the account and who the expected following might be.

Posts

It is possible to post or share original content that you have created, or reshare content that others have created/shared. It is usually possible to reshare content to your followers in different

ways. For example, interacting with a post such as 'liking' content on LinkedIn currently reshapes it to your feed and potentially to your followers' feed. Posts are named differently on different platforms, for example, a tweet (Twitter) or video (YouTube, TikTok).

Sharing content that others have created brings that content within the scope of the ABPI Code for which the company is responsible.

Further Engaging with, and Reacting to Posts

Social media platforms also enable followers to further engage with, or react to, posts.. This can take different forms, including expanding an image, watching a video or choosing to include a reaction from an exhaustive list of emoticons including a simple 'thumbs up' or 'heart' to like a post. The more that posts are engaged with and/or reacted to, the increased likelihood that they will be prioritised by platform algorithms and shown as recommended content to others. Sometimes reacting to a post can also directly reshare the content to your followers, for example, liking content on LinkedIn, Twitter and Facebook can reshare content to your followers as a notification.

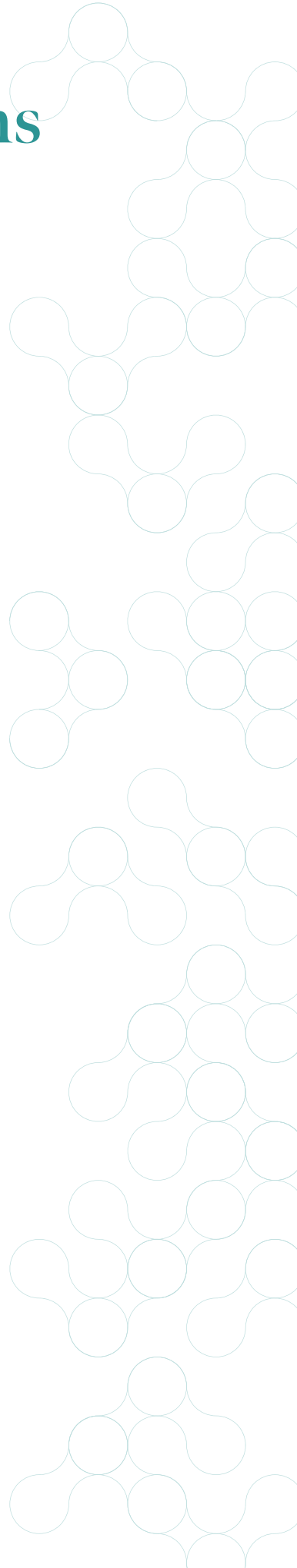
Paid Earned Shared Owned (PESO Model)

These concepts are useful to consider when conducting social media activities and whether the social media is owned, earned or paid media.

Paid media are posts that the company pays to share, such as social media display advertising.

Owned media are posts shared through accounts that are directly owned and controlled by the company.

Earned or Shared media are posts which other accounts (that are not controlled or paid by the company) choose to reshare that supports the company and company activities. Note that if the pharmaceutical company decides to interact/engage with the post, for example, by reposting or sharing the content, then the company will likely be responsible for the content under the ABPI Code and the content is likely to be considered as company advertising.



Appendix B

References

Legislation

As referred to on Page 65 of the 2021 ABPI Code:

The Human Medicines Regulations 2012 as amended 2012 No. 1916

The Human Medicines (Amendment) (No. 2) Regulations 2014 No. 1878

The Consumer Protection from Unfair Trading Regulations 2008 2008 No. 1277

Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as amended by Directive 2004/27/EC

Bribery Act 2010

Data Protection Act 2018

Codes

The Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry 2021

The International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA) Code of Practice

The European Federation of Pharmaceutical Industries and Associations' (EFPIA) Code of Practice

The UK Code of Non-broadcast Advertising and Direct & Promotional Marketing (CAP Code)

PAGB Advertising Codes for Medicines

Guidelines

Advertising and Promotion of Medicines in the UK (2020) – The Blue Guide (Medicines and Healthcare products Regulatory Agency).

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How to get in touch

Alex Fell, Director PMCPA
Tannyth Cox, Deputy Director PMCPA

PMCPA
2nd Floor
Goldings House
Hay's Galleria
2 Hay's Lane
London
SE1 2HB

Telephone: +44 (0) 0207 747 8880
www.pmcpa.org.uk
<https://twitter.com/PMCPAUK>
Enquiries should be submitted to info@pmcpa.org.uk

The Prescription Medicines Code of Practice Authority (PMCPA)

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