1 June 2023

Questions & Answers from the PMCPA's Social Media Webinar on 9 February 2023

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.

PRINCIPLES

1. Regarding transparent disclaimers on social media, what is PMCPA's view on #ad as required under the CAP code?

Promoting a prescription only medicine to the public is prohibited by UK law (as well as by European law). 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.

2. Are pharmaceutical companies responsible for third party content forever or is there a cut off time that they are responsible for?

As the case examples (CASE AUTH/3226/7/19 and CASE AUTH/3583/11/21) used during the training illustrate, a pharmaceutical company might be considered to be responsible for the actions of its third-party even after the end of the contract. For this reason, it is important that companies have appropriate contracts in place and exercise oversight over their third-parties with particular focus on contract termination and robust follow-up procedures which might include obtaining confirmation from the third party in relation to material destruction, where relevant, upon cessation of the contract.

3. What do you consider to be a "timely manner" for monitoring posts and comments?

This is a matter of company policy, paying particular attention to its pharmacovigilance requirements and own social media community guidelines in addition to ensuring compliance with all relevant codes, laws and regulations.

4. What is considered "an inappropriate comment" that requires deleting?

This is a matter of company policy. The types of 'inappropriate comments' that should be deleted go beyond the scope of the ABPI Code so the PMCPA cannot advise fully but it is likely to include inaccurate or misleading information, claims or disparaging comments, as

well as any content that is discriminatory, obscene, harassing, hateful, threatening, profane or personally abusive.

5. Does the PMCPA assume that a member of the public will know that [company name] is a pharmaceutical company? Or must the nature of the company's business be stated?

The ABPI Code does not require that the nature of the company's business (e.g. Company X is a pharmaceutical company) is stated. 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.

6. Will a pharmaceutical company be held responsible for its employee liking a promotional post made by another pharmaceutical company?

It would depend on the relationship between the two pharmaceutical companies. If there was no relationship between the two pharmaceutical companies, it is difficult to see how one could be held responsible for promoting the other company's medicines; it is a well-established Code principle that a pharmaceutical company cannot be found to be promoting another company's medicines. However, it is important to note that this does not preclude the company from potentially being responsible for its employees' actions on social media if such activity falls within the scope of the Code, for example, if the activity disparages the medicines or activities of another pharmaceutical company.

7. Is self-validation sufficient or is double validation needed e.g. GMC?

The guidance in relation to signposting states that 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). In relation to signposting to invite health professionals to register for promotional meetings, the guidance also states that more formal validation for meeting registration/attendance might be required to ensure only appropriate attendees attend the meeting itself.

It is also worth bearing in mind the supplementary information to Clause 16.1 which states that unless access to promotional material about prescription only medicines is limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This is to avoid the public needing to access material for health professionals unless they choose to. The MHRA Blue Guide states that the public should not be encouraged to access material which is not intended for them.

8. What is considered "good" monitoring protocol?

This is a matter of company policy.

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.

9. When a therapy area only has one product, e.g rare diseases, is there some leniency in some of the Code principles given that material will indirectly link to product?

The ABPI Code applies regardless of the therapy area. Appendix 7 of The MHRA Blue Guide states Disease Awareness Campaigns (DACs) for diseases or conditions where there is only one, one leading or few medicinal treatments potentially draw attention to one medicinal product, albeit indirectly, regardless of whether it is referred to or not. DACs in these circumstances require particular care. It is particularly important that these campaigns focus on health and disease education, with details of where to get appropriate advice.

10. How does the promotion of UK online pharmacies work? E.g. if you google the brand name of a prescription only weight loss medication it comes up with search results for online pharmacies advertising the medicine for sale to the public.

The ABPI Code covers the activities of pharmaceutical companies. Promotion by pharmacies and clinics, if there is no involvement from a pharmaceutical company, will not be within the scope of the ABPI Code and therefore will not be within the PMCPA's jurisdiction. It might be brought within scope if, for example, a pharmaceutical company employee engages with the content and further disseminates the information. Nonetheless, UK advertising law (as outlined in Part 14 of the Human Medicines Regulations 2012) applies to everyone. MHRA, acting on behalf of Health Ministers, is obliged to consider any complaints made to it about the advertising of medicines. Appendix 6 of the MHRA Blue Guide on the Advertising and Promotion of Medicines in the UK outlines how treatment-service providers such as online pharmacies that may supply Prescription Only Medicines can promote the service and consultation they provide. Chapter 5 of the Blue Guide outlines how over-the-counter medicines may also be lawfully promoted to the general public. The Blue Guide also summarises how MHRA works closely with other regulatory bodies to protect the public from inappropriate advertising, such as the General Pharmaceutical Council and Advertising Standards Authority.

11. If a company partners with a charity for example, would the charity employees need guidance?

Pharmaceutical companies should ensure that all third-parties they work with, including charities, understand how the ABPI Code might apply to its activities with the pharmaceutical company. This is typically done through contracting as well as training/briefing as required.

Clause 1.24 gives the Code definition of a third-party and states that Companies are responsible under the Code for the acts and omissions of their third parties which come within the scope of the Code, even if they act contrary to the instructions which they have been given.

12. Will the principle of development mentioned for the legitimate exchange of medical and scientific information during the development of a medicine (LEMs) be generally used to assess whether a post applies to POM or not?

Whether a medicine is considered a POM under the Code will be based on its legal classification in the UK. UK legal requirements refer to products with or without a marketing authorisation with no further distinction. LEMs is a very limited exception of an activity that might be carried out in relation to a medicine prior to the grant of its marketing authorisation as set out in the supplementary information to Clause 3.1.

13. It is often not possible to control things like the font size on social media (e.g. the font size of the video description on YouTube. How is that being taken into account and will companies be ruled in breach based on the factors inherent in the user interface of the social media channel?

It is for pharmaceutical companies to understand the different features, functions, terms and conditions for the social media channels it uses and engages with to ensure they comply with all applicable Codes, laws and regulations. Companies should only use a particular platform if they are confident they can meet all the requirements of the Code and the terms and conditions of that platform.

14. Do you need to state the funding organisation for grant funded activities on social media? E.g. if we are running an CME-accredited MS programme funded by an IME grant from (Pharmaceutical company), do we need to state that (the pharmaceutical company) have supported the activity with a grant in any tweet/LinkedIn etc that we use to promote the meetings?

Yes. Clause 10.9 of the 2021 Code states that when events/meetings are sponsored by pharmaceutical companies, that fact must be disclosed in all the material relating to the events/meetings and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset.

15. If a global employee is physically based in UK, can they approve posts to go on a US based account and not bring it into the scope of the code?

If an employee based in the UK is part of an internal company approval process for a social media post that will be posted on a non-UK company account (e.g. the company's US corporate Twitter account) and the post does not make reference to the availability or use of a medicine in the UK, it will likely be outside the scope of the UK Code unless it is brought into the scope e.g. by a UK or UK based employee engaging with the post.

16. Does the responsibility for employees' behaviour also include any potential third party employee? Like an agency's employee that's working with a pharmaceutical company?

A pharmaceutical company will generally be considered responsible for work related posts on social media by its employees, contractors, consultants and third party agencies which include the agency's staff and those sub-contracted by the agency.

17. On the pharmacovigilance section, it is stated that "signpost users to how they can report an AE [website address]" - can you please clarify if you mean MHRA website?

In relation to social media channels/accounts/posts etc for which pharmaceutical companies are responsible, the requirements of Clauses 12.9 and 26.4 in relation to the adverse event reporting statement apply.

In relation to social media channels/accounts/posts etc for which pharmaceutical companies are not responsible, the MHRA advice is that pharmaceutical companies should signpost the social media user as to how they can report the adverse event to the MHRA (MHRA website address).

18. Do you think all posts should be examined by a Final Signatory before posting regardless of the topic?

The PMCPA recommends you consult Clause 8 of the 2021 ABPI Code and its supplementary information to determine which posts require certification. The supplementary information to Clause 8.3 states that material issued by companies which is not required to be certified under the Code should be examined by a signatory or an AQP, who needs not be a signatory, to ensure that it does not contravene the Code or the relevant statutory requirements.

19. I understand the LinkedIn implications but if an employee likes or posts something product related on more of a personal social media platform such as Facebook or Instagram, and their profile does not detail the company they work for, would this still be considered in breach?

Pharmaceutical companies should assume that the ABPI Code would apply to all work related, personal social media posts/activity by their employees regardless of the platform unless, for very clear reasons, it could be shown otherwise.

20. If a global entity posts content to a global audience, but some of the followers are based in the UK, does that put the content in scope?

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. Information directed at a UK audience is likely to be within scope of the UK Code unless, for very clear reasons, it could be shown otherwise.

21. Is self-validation of patient status sufficient to access materials aimed at patients already prescribed a medicine?

Yes. The MHRA Blue Guide states that copies of appropriate materials may also be made available on a company internet site for reference purposes. If a website provides both information for the general public and copies of materials aimed at patients prescribed the product, the sections for each target audience should be clearly separated and clearly marked for the target audience. Adequate non-promotional information must be provided for general members of the public so that individuals do not need to access sections designed for patients unless they choose to seek further detailed information. Members of the public should not be encouraged to access information which is not intended for them.

LINKS

22. What happens if a non-promotional post links to a promotional website but has an HCP only gateway - is that okay?

The PMCPA considers each case on its own merits. Generally, if a non-promotional post e.g. disease awareness linked to a promotional website for a product, this is unlikely to meet the definition of disease awareness and may be considered disguised promotion.

Furthermore, the Code 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. Material should be tailored to the audience to whom it is directed. In some instances, you may be able to use signposting, however, you will have to use all the safeguards that apply to signposting as referred to in the PMCPA social media guidance.

It is also worth bearing in mind the supplementary information to Clause 16.1 which states that unless access to promotional material about prescription only medicines is limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This is to avoid the public needing to access material for health professionals unless they choose to. The MHRA Blue Guide states that the public should not be encouraged to access material which is not intended for them.

MEETINGS ADVERTISEMENTS

23. What about an advertisement by a private clinic promoting a webinar on LinkedIn where HCPs will talk about Prescription only Medicines (POMs)?

The ABPI Code covers the activities of pharmaceutical companies. Promotion by pharmacies and clinics, if there is no involvement from a pharmaceutical company, will not

be within the scope of the ABPI Code and therefore will not be within the PMCPA's jurisdiction. It might be brought within scope if, for example, a pharmaceutical company employee engages with the content and further disseminates the information. Nonetheless, UK advertising law (as outlined in Part 14 of the Human Medicines Regulations 2012) applies to everyone. MHRA, acting on behalf of Health Ministers, is obliged to consider any complaints made to it about the advertising of medicines, looking at the facts of each case on their own merit.

DISEASE AWARENESS

24. What if you want to post on social media on a therapy area which you will eventually be launching but does not contain any information on the drug, only the therapy area?

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.

25. Can employees engage with disease awareness campaigns that are certified as required by the UK Code?

Pharmaceutical companies should have policies on how employees may interact with such posts. It might be permissible for employees to react to, or share, disease awareness posts intended for the public if that post has been certified as required by the UK Code. Note that if employees add their own comments when sharing the material, they will have changed the final form and therefore it will no longer be considered certified as required by the UK Code. Also, additional comments on dissemination may change the meaning of the post and thus the addition of any comments by the employee should be prohibited.

PROFESSIONAL PROFILES AND JOB POSTINGS

26. Can an employee add a publication they authored as company employee to their personal LinkedIn account? not as a feed post but for instance to the job description field, so someone would have to go into the profile to find it?

Employees should exercise judgment and consider the purpose of adding the publication. Information in employee profiles 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. It might be permissible to include publications within the more detailed 'Experience' section of their 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.

27. Can any advertisement for prescription drugs be submitted for awards? And if the awarding company posts about it is still responsibility of the pharmaceutical company?

Advertisements for prescription medicines may be submitted for appropriate trade awards. The PMCPA's view is that there is a difference between putting examples of pharmaceutical promotional material on an advertising agency or awards website in a section clearly labelled in that regard and putting the same on open access social media platforms. It is the responsibility of the pharmaceutical company to ensure there are adequate safeguards in place to prevent the material from being shared with the public e.g. to prevent it from being posted on social media by its third parties for which it is responsible.

28. If an affiliate employee outside of the UK includes a brand name in their job title on social media and UK employees engage with the individual's handle, does this fall under the jurisdiction of the code

It would depend on the nature of the interaction and the result of that interaction. Note that rules and regulations governing prohibition of the promotion of prescription only medicines to the public are broadly consistent across Europe.

CORRECTING MISINFORMATION AND INACCURACIES

29. As a company should we have to correct posts, even if it was not posted by the company itself?

Responding to misinformation or inaccuracies about POMs published on social media is a difficult area and is a question of company policy. Simply adding a cross-reference to the regulatory documents such as Summary of Product Characteristics (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?

30. On correcting misinformation/correcting inaccuracies - would it be acceptable to use the same approach (cross-referencing to SmPC/PIL) if it has come to our attention that a Patient Advocacy Group (PAG) website contains inaccuracies about product information and still be abiding by clause 27.4?

Responding to misinformation or inaccuracies about POMs published online is a difficult area and is a question of policy for a company. Clause 27.4 does not preclude a company from correcting factual inaccuracies. In the first instance, we would recommend contacting the PAG to highlight the error.

SIGNPOSTING

31. For signposting - how would you advise signposting for press releases intended for lay members of public? Can these be added to the website (e.g. some companies make announcements re NICE approval)

The supplementary information to Clause 26 refers to press releases for the media (which may be the medical media or lay media) or financial information to inform shareholders and the stock exchange etc. Pharmaceutical companies should note there is a difference between making a press release/ information available 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. The distribution of press releases regarding a POM to the general public on social media is likely to be seen as promotion of a POM to the public which is prohibited by the Code and UK law. When signposting to a press release, there should be clear signposting of the intended audience the post is targeted at and the press release should be housed on the pharmaceutical company's or another website in a section tailored to the intended audience and should clearly state the intended audience. 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. The audience is required to self-validate before accessing the material eg on the pharmaceutical company's website.

HASHTAGS AND TAGGING

32. Hashtags are relatively new. I understand that history of the hashtag is important. Where you use a hashtag that has been used inappropriately in the past - has the PMCPA any views for how long that history needs to be take into account. If use twenty or thirty years ago, for example, would that history then still need to be taken into account? Are their views after a certain length of time after which you could no longer take the past use of a hashtag into account?

This is a matter for company policy. 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. Each case is considered on its own merits, taking into account all of the circumstances including, amongst other things, the content of the hashtag feed and the chronology of the hashtag link.

33. You say a pharmaceutical company "might" not have to ask for permission from the organisation they are tagging on social media. When do we have to ask for permission?

Whilst a platform's T&Cs might enable you to tag another account without permission, it may be advisable for a company to ask before tagging another account, if it is not already covered in a written agreement between the parties, particularly if, for example, the 'tag' suggests any form of endorsement to the content of the post, or refers to an activity that the parties are involved in.

PRODUCT AND PIPELINE MILESTONES

34. Is it mandatory for journalists to self-validate before accessing global corporate press releases on product & pipeline milestones?

If a journalist or investor, without being prompted, searches for relevant press releases on a company website they should be housed in a clearly labelled section of the company corporate website clearly stating the intended audience so it is clear who the information is intended for before accessing it.

Pharmaceutical companies should note there is a difference between making a press release/ information available 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. The distribution of press releases regarding a POM to the general public on social media is likely to be seen as promotion of a POM to the public which is prohibited by the Code and UK law. If signposting to a press release that is housed in a section of your corporate website by way of a social media post, the company is potentially directing a broader than intended audience to it, and therefore self-validation is recommended as stated in the guidance. When signposting to a press release, there should be clear signposting of the intended audience the post is targeted at and the press release should be housed on the pharmaceutical company's or another website in a section tailored to the intended audience and should clearly state the intended audience. 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. The audience is required to self-validate before accessing the material eg on the pharmaceutical company's website.

PATIENT SUPPORT

35. For the patient materials section, instead of using Youtube URL via restricted access, could you use a self-certifying section of the company website to store these?

The MHRA Blue Guide states that companies may provide non-promotional information to support patients who have been prescribed a particular medicine and that copies of appropriate materials may be made available on a company internet site for reference purposes. It further states that if a website provides both information for the general public and copies of materials aimed at patients prescribed the product, the sections for each target audience should be clearly separated and clearly marked for the target audience.

Adequate non-promotional information must be provided for general members of the public so that individuals do not need to access sections designed for patients unless they choose to seek further detailed information. Members of the public should not be encouraged to access information which is not intended for them.

CLINICAL TRIAL RECRUITMENT

36. In the clinical trial recruitment section it states that a link should be provided to relevant information from the NHS/Body organsising/conducting the trial. Would it be acceptable to link to clin trial.gov as here would mention product?

The purpose of providing a link to the NHS/Body organising/conducting the trial is to enable a patient to learn more about a trial from a UK recruiting body to see if they might be eligible to participate. Such information is not generally the focus of clinicaltrials.gov, and therefore it might not be acceptable to link to this in a clinical trials recruitment post.

37. What does it mean to place something on social media inside the UK? Is it if the person who posted it is based in the UK, the balance of followers?

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