PMCPA | Prescription Medicines Code of Practice Authority

GUIDANCE ABOUT DIGITAL COMMUNICATIONS

INTRODUCTION

In the UK, the promotion of prescription medicines to health professionals is carried out within a robust regulatory framework to support high quality patient care. The ABPI Code of Practice for the Pharmaceutical Industry, administered by the Prescription Medicines Code of Practice Authority (PMCPA), is the self-regulatory code which applies, *inter alia*, to the promotion of prescription medicines to health professionals and to the provision of information about prescription only medicines to the public. The Code reflects and extends beyond UK law. This guidance reflects the requirements of the 2016 Code.

The pharmaceutical industry is highly regulated. In stark contrast, digital communication such as social networking sites, including Twitter, Facebook, Instagram, Wikipedia, Pinterest and WhatsApp, blogs and discussion forums, and other user generated content is largely unregulated. Indeed, for many other industries this can be part of the attraction for engaging in this way. The challenge is how these tools can be used by the pharmaceutical industry.

Pharmaceutical companies want, and indeed should be able, to use digital media. However, unlike other industries, which can promote their products to all, pharmaceutical companies are prohibited from promoting prescription only medicines to the public. Therefore, pharmaceutical companies need to identify ways of utilising digital communications whilst complying with this restriction. At the same time, companies must have policies and procedures in place to ensure that personal use of email, Twitter, all social media and the like by staff does not unwittingly lead to a breach of the Code.

Companies can use any method of communicating to any audience provided relevant requirements of the Code are followed.

RELEVANT CODE REQUIREMENTS

A good starting point when deciding which clauses are relevant is to identify the audience for the communication. Another relevant factor, particularly if the audience includes the public, is whether the material is to be proactively distributed or reactively available, ie in response to a request.

For example, a company can provide a summary of product characteristics (SPC) for a prescription only medicine to a patient on request or can publish that SPC on its website. Such activity would be regarded as non-promotional. However, if the company was to proactively distribute the SPC at a patient organisation meeting that might be regarded as promoting a prescription only medicine to the public albeit with a document which, in itself, is non-promotional.

It has been established that EU law prohibiting promotion of a prescription only medicine to the public applies beyond commercially interested parties, ie pharmaceutical companies. The ABPI Code only applies to pharmaceutical companies.

The following is a list of the most relevant clauses of the Code; it is not comprehensive. Other clauses, particularly Clause 7, are also relevant but have not been mentioned in detail in this section.

Promotion, as defined in Clause 1.2, is 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 1.2 also lists items and activities which are specifically included or excluded from the definition of promotion.

Excluded from the definition of promotion are replies to individual enquiries from health professionals or other relevant decision makers, but only if they relate solely to the subject matter of the enquiry, are accurate and do not mislead and are not promotional in nature.

In order to take the benefit of this exemption the company has to demonstrate that the reply is a response to an unsolicited enquiry. It would not do so if that reply was made public, for example as one of a number of frequently asked questions and answers listed on a company website.

Clause 3 prohibits promotion of a medicine prior to the receipt of its marketing authorization. It also requires that promotion is in accordance with the terms of the marketing authorization and not inconsistent with the SPC.

Clause 9.9 states that telephone, text messages, email and other electronic data communications must not be used for promotional purposes without the prior permission of the recipient. Companies are also required to provide information for the recipient as to how to unsubscribe to emails.

Clause 9.10 requires that material relating to medicines and their uses, whether promotional in nature or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that company.

Clause 26 is about relations with the public and the media. Prescription only medicines cannot be promoted to the public. Whilst promotion is prohibited, factual and balanced information about prescription only medicines can be made available to the public either directly or indirectly. However, statements must not be made for the purpose of encouraging members of the public to ask a health professional to prescribe a specific prescription only medicine. The quality standards in Clause 7 also apply to information provided to the public.

The supplementary information to Clause 26.2 permits companies to post on their websites reference information for the public about prescription only medicines which have marketing authorizations. The primary purpose of the reference information is to be a library resource for the public. This information can include:

- regulatory information comprising the SPC, the package leaflet (PIL) and the public assessment report (PAR) where such a document exists. Provision of this information, as a minimum, is seen as good practice
- registration and other studies

- medicine guides
- disease information
- specific medicine information
- material supplied for health technology assessments to bodies such as the National Institute for Health and Care Excellence (NICE), the All Wales Medicines Strategy Group (AWMSG) and the Scottish Medicines Consortium (SMC).

The reference information must represent fairly the current body of evidence relating to the medicine and its benefit/risk profile.

Some UK pharmaceutical companies do not provide all of this information on their websites or even links to where it could be found, for example to the eMC (an electronic medicines compendium (www.medicines.org.uk/emc)). Clause 26 differentiates between proactive information which is pushed at the recipients (for example advertisements in journals) reference information as detailed above and reactive information which is supplied to a member of the public in response to a direct request.

Clause 26 also refers to the provision of information about a particular medicine to patients who have been prescribed that medicine.

With regard to enquiries from the public, companies are permitted to provide information appropriate to support the use of medicines and enhance patient welfare. Examples and further advice on dealing with requests for information or advice on personal medical matters is given in the supplementary information to Clause 26.4.

If a company is working with a patient group then Clause 27 becomes relevant and must be followed including the requirement for a written agreement.

Companies must also ensure that material and activities are certified in accordance with Clause 14.

However, much of the Code applies irrespective of the method of communication. If a product is promoted to health professionals prescribing information and other obligatory information must be supplied (Clause 4).

A key consideration for any interaction is pharmacovigilance. The Code has only limited requirements in this regard, in that promotion has to include a reference to reporting adverse events (Clause 4.10) as does certain information for patients (Clause 26.3). In addition 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 16.2). The current position in the UK is that if a pharmaceutical company (or an agent working on its behalf) becomes aware of an adverse event associated with its product then data about it has to be collected. It should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) if appropriate. Further information can be obtained from the ABPI.

GUIDANCE

The PMCPA cannot approve any materials or activities. It can, however, give informal guidance based upon its interpretation of the Code and, where available, the outcomes of past cases. If a complaint were received about a matter upon which advice had been given, it would have to be considered in the usual way and on its own particular merits.

It is important to remember the principle that a pharmaceutical company is responsible under the Code for any activities carried out on its behalf by a third party even if that third party acts beyond the scope of its contract.

Given that the Code applies to communication of any kind, many of the proposals for digital communication are already covered by the Code. A few changes were made for inclusion in the 2015 Code. There have been some complaints about digital communication and the case reports are available on the PMCPA website.

Use of Email

Pharmaceutical companies can email promotional material to health professionals and other relevant decision makers, provided that the recipient has actively given prior permission for such emails to be sent (Clause 9.9). The wording used by the company, or by an agency on its behalf, to gain such permission is crucial and should be carefully scrutinised. The wording should form part of the job bag for the promotional email and must show that the health professionals, and other relevant decision makers to whom the email will have been sent, have already given fully informed consent. In seeking consent, it must have been made abundantly clear to the respondent that agreement would result in the receipt of promotional emails. Lack of clarity in this regard is likely to lead to a breach of Clause 9.9.

Promotional emails should not include the statement 'Forward to a colleague' or similar. The Authority is concerned that suggesting to recipients the possibility of forwarding the email to a colleague would not comply with the need to ensure prior permission from the onward recipient before the promotional email is resent. In forwarding the email original recipients would be acting at the company's direction in that regard and so the company would be responsible under the Code for their action.

The supplementary information to Clause 9.9 states that where permission to use emails for promotional purposes has been given by a recipient, each email sent should inform the recipient how to unsubscribe. However, with regard to responding to emails, the supplementary information to Clause 9.9 further states that an unsolicited enquiry received by email, or an unsolicited enquiry received by post which includes an email address, can be responded to by email without specific permission, consent to do so being implied in such circumstances. There is no need to inform recipients as to how to unsubscribe to an email response to an enquiry.

Companies must ensure that emails are only sent to those whose need for, or interest in, them can be reasonably assumed (Clause 11.1) and mailing lists must be kept up-to-date (Clause 11.3). Requests to be removed from promotional mailing lists must be complied with promptly and no name restored, except at the addressee's request or with their permission. Promotional emails are often sent via agencies which maintain the relevant mailing lists. In that regard companies are reminded that if the third party sends material to those whose need for, or interest in it cannot be reasonably assumed, or if the agency fails to keep its mailing lists up-to-date, the pharmaceutical company itself will be held responsible under the Code; it is an established principle under the Code that pharmaceutical companies are responsible for work undertaken by third parties on their behalf.

The supplementary information to Clause 12.1 states that promotional material sent electronically such as emails must not give the impression that they are non-promotional. The identity of the responsible pharmaceutical company must be obvious. Once opened, the recipient should not have to view the email in a web browser to see crucial information such as to understand who sent the email and what it is about.

Companies should put themselves in the recipient's place to see what initial impresssion they would have of the email if they received it, bearing in mind that all of the information is unlikely to be seen on one screen.

Clause 4.1 of the Code requires all promotional material (except abbreviated advertisements which are not permitted on the internet (Clause 5.2) and thus could not be sent by email), to include prescribing information as listed in Clause 4.2. Whenever a health professional reads promotional material he/she must at the same time have access to the relevant prescribing information. In digital material the prescribing information could be provided by the use of a link, but such links should only be provided when the item is likely to be viewed online. Given that emails will often be read offline then the requisite information should be provided as part of the item itself, or as a link which does not require the reader to be online.

And finally…the use of email has become familiar to us all to the point where it is widely used for both business and social contact. Emails are generally regarded as less formal than traditional letters and often casual language is used. Any email sent to a health professional, or other relevant decision maker, about a matter which relates to their professional role must not breach the Code through the use of exaggerated claims, immoderate language and the like. A practical rule of thumb might be that if the message could not be sent on company headed notepaper, then it should not be sent by email.

The Q&As should be read in the light of the brief details about particularly relevant clauses of the Code listed above. In addition this is a developing area and as well as the letter of the Code, companies should bear in mind the spirit of the Code.

1. Can pharmaceutical companies communicate with health professionals via social media?

The use of social media to promote, increase awareness and encourage engagement with health professionals about prescription medicines is very likely to be seen as promotion as set out in Clause 1.2. Pharmaceutical companies are allowed to promote their medicines to health professionals and the Code will apply whether the setting is a face-to-face meeting, through the distribution of paper-based or electronic promotional material, on a social networking site, in an online forum or by email.

If a company wanted to promote a medicine via twitter it would have to ensure that if the medicine was prescription only, the audience was restricted to health professionals and that the message, in addition to any link to further information, complied with the Code. In addition companies would also have to ensure that recipients had agreed to receive the information. Given these restrictions and the character limit on twitter, it is highly unlikely that the use of this medium to promote prescription only medicines would meet the requirements of the Code.

Using twitter to alert health professionals about the publication of a study on a medicine is likely to be considered promotion of that medicine.

The supplementary information to Clause 9.9 states that where permission to use emails for promotional purposes has been given by a recipient, each email sent should inform the recipient how to unsubscribe. However, with regard to responding to emails, the supplementary information to Clause 9.9 further states that an unsolicited enquiry received by email, or an unsolicited enquiry received by post which includes an email address, can be responded to by email without specific permission, consent to do so being implied in such circumstances. There is no need to inform recipients as to how to unsubscribe to an email response to an enquiry.

2. Can pharmaceutical companies use social media to provide information to the public?

Yes, providing the material complies with the Code – particularly Clause 26.

- **What about providing information to patients taking their medicines?**

Yes again, providing the material complies with the Code. Recipients would have to agree to receiving material. That material must not promote a prescription only medicine but could go into more detail as the patient would already be taking that medicine.

- **Can companies run discussion forums?**

If a company facilitated a discussion forum on a third party website, or hosted one on its own, it is likely to be responsible under the Code for its content. Before undertaking such an activity the company must be confident that it can moderate the site such that the only content to appear complies with the Code. The intended audience (ie health professionals or the public) would need to be identified so that the relevant requirements could be complied with.

3. What if a pharmaceutical company provides an unrestricted grant to a doctor or patient group to develop a social media site on a disease area? A declaration is made on the site that sponsorship is from the company but the content is that of the doctor/patient group.

It does not appear that the sponsorship/support described in the question is an unrestricted grant.

The advice given about arm's length arrangements on the PMCPA website is relevant. This states that it is possible for a company to sponsor material, produced by a third party, which mentions its own products, and not be liable under the Code for its contents, but only if, *inter alia*, there has been a strictly arm's length arrangement between the parties. In practical terms the arrangements must be such that there can be no possibility that the pharmaceutical company has been able to exert any influence or control over the final content of the material.

Factors which might mean there had not been a strictly arm's length arrangement would include, but not be restricted to:

- Initiation of the material, or the concept for it, by the pharmaceutical company

- Influence from the pharmaceutical company on the content/balance/scope of the material
- Choice or direct payment of the authors by the pharmaceutical company.

Use of the sponsored material for a promotional purpose will mean that it is subject to the Code.

The role of the company needs to be made clear (Clause 9.10) and the company should not promote the social media site in any way unless all of the content complies with the Code. If a company is working with a patient group then Clause 27 becomes relevant and must be followed including the requirement for a written agreement and disclosure of payments. It would be difficult for companies to sponsor such sites where it could reasonably be expected that participants would advocate the use of that company's medicines.

4. When is a company liable for collecting and reporting adverse events that are identified on a site it sponsors?

Companies are obliged to collect adverse events and report them if appropriate so any interaction must include plans for reviewing the site to meet pharmacovigilance requirements.

5. Can companies correct Wikipedia?

This is difficult and is a question of policy for a company. Simply adding a cross reference to the regulatory documents such as SPCs and PILs either on a company site or to the eMC, would 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 company could refer readers to its reference information (as defined in the supplementary information to Clause 26.2) about the medicine by means of a link to an appropriate landing page. Clearly all the reference information needs to comply with the Code. (NOTE This introduces a limited new use for reference information – a proactive use rather than a reactive use).

Correction of material might lead to more challenges as it would be beholden on the company to ensure that everything was correct including statements about competitor products – otherwise why correct some inaccuracies but not all? Most people using Wikipedia assume that it is not verified and once a company starts such verification it might be difficult not to do it all.

6. Can companies link to other websites?

This is covered in Clause 28.6. Any website chosen by a company to link to from its website should stand up to scrutiny. For example, why has one patient organisation's site been chosen rather than another (which is more popular)? Is it because it is more positive about the company's product? Companies should be confident about the choice of linked sites and that these do not promote prescription only medicines to the public. It is preferable to link to the homepage.

If a company included website addresses in advertising to health professionals etc then the content of that website would be potentially subject to the Code.

7. What about the use of search engine optimisation and metadata?

Search engine optimisation ensures that the company's material is listed in, for example, the top ten outcomes following a search on Google etc. It includes the use of metadata (see below).

Generally speaking it would not be unreasonable for a company to try to ensure that its sites are ranked high on lists when the search is for that company or one of its medicines (brand or generic).

It would be questionable for a company to try to ensure that its product website was ranked highly when a more general search term was used. Such activity might be relevant if a complaint were received that a company was promoting a prescription only medicine to the public or encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine.

Metadata is the information about the webpage and is used, *inter alia*, by search engines to rank a website's relevance to the search term used and is then displayed in the results to help readers choose the most relevant website. Metadata should reflect the content of the site and not be

promotional. The use of metadata to link a specific medicine to a disease awareness site is likely to be unacceptable.

8. What about use of blogs?

Blogs are a popular communication tool to enable people and companies to express and share their views on the Internet.

If a company established or were to sponsor a blog about a medicine or a therapy area, then it would need to ensure that all of the information contributed complied with the Code. It would be unacceptable, for example, if someone contributed material about the unlicensed use of a product to a blog sponsored by the pharmaceutical company which marketed the product. This could be seen as the company promoting the product outside its marketing authorization as the company would, in effect, be distributing the information. Any involvement of a pharmaceutical company in the establishment or sponsorship of a blog must be declared.

Given that, by their very nature, blogs are for contributors to freely and spontaneously express their personal views on a subject, pharmaceutical companies should not sponsor such sites on the Internet if they were intended, or could reasonably be expected, to discuss medicines and their uses as it would be impossible to guarantee their compliance with the Code.

9. What about company employees contributing to non company discussion forums etc?

Potentially any activity by a pharmaceutical company employee, or even by an employee of an agency acting on its behalf, is subject to the Code. Thus the activities of individuals also need to comply with the Code.

Companies need to have clear policies about such activities. Transparency and openness are key features of the Code and its spirit.

10. Can companies run and/or support online meetings?

Yes. Meetings have to comply with Clause 22 in that the education must be the prime attraction. Clearly the requirements for subsistence are not relevant. Companies cannot of course pay delegates to attend meetings. Sponsorship must be declared.

The publication of the outcome of a meeting must comply with the Code including the prohibition of the promotion of unlicensed medicines/indications. If a company published meeting discussions these are likely to be viewed as promotion.

11. What about the activities of an overseas parent company or affiliated company?

It is a well established principle that the UK company is responsible under the Code for activities of its overseas parent or affiliate in the UK or with UK health professionals abroad.

If a complaint were made it would be taken up with the local company.

12. What if an overseas parent company placed information on the Internet?

Clause 28.2 states that information or promotional material about prescription only medicines which is placed on the Internet outside the UK would be regarded as coming within the scope of the Code if it was placed there by a UK company or an affiliate of a UK company or at the instigation or with the authority of such a company and it specifically referred to the availability or use of the medicine in the UK.

Cases about tweets issued by global head offices of pharmaceutical companies have been considered by the Panel. The global offices were not based in the UK and the Panel decided that as a non-UK company had registered the Twitter accounts in question and the UK affiliate had no role in the generation, approval or publication of tweets on the account, or any material linked to the tweets, did not direct a UK audience to the account and as neither the tweets nor any linked material specifically referred to the use of prescription only medicines in the UK, then the tweets and linked material were not covered by the requirements of Clause 25.2 (now 28.2). Consequently the tweets and linked material did not come within the scope of the Code.

The tweets would be covered by a code of practice which is likely to be that of the country where the parent company or affiliate generating the tweets resides.

13. What should be considered when certifying digital material?

Clause 14 sets out the requirements for certification under which the final form of materials have to be certified before use by one person who must be either a registered medical practitioner or a pharmacist registered in the UK. In addition, the signatory must not be responsible for developing or drawing up the material.

Care needs to be taken when certifying dynamic content to ensure that each piece meets the requirements of the Code. In addition, consideration needs to be given in relation to dynamic content and how it is displayed or presented within the context of the website.

This would include metadata (Q7).

14. What about the effect of using different devices such as a smart phone, tablet, laptop etc?

Companies should ensure digital content displays correctly across different platforms and devices . If content is designed for only one device/platform this should be made clear to readers.

15. What about privacy issues?

Companies need to ensure that they comply with relevant legal requirements including data privacy law. Information collected from websites should meet regulatory requirements. Clear information relating to the use of tracking technologies should be given.

16. Can Twitter be used during conferences?

The content of tweets sent by companies and employees is potentially subject to the Code. The content of tweets would have to be suitable for the public. Using Twitter to draw attention to a presentation at a meeting could potentially be seen as promotion (see Q1).

17. What about using social media to correct inaccuracies about medicines?

Responding to inaccuracies about medicines in social media posts is a difficult area and Q5 above is relevant.

The PMCPA welcomes suggestions and queries from pharmaceutical companies about what they would like to do with digital communications and in particular, social media. Requests for information and guidance are treated confidentially and the PMCPA is happy to work with pharmaceutical companies and others to provide informal guidance about the Code.

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