PMCPA | Prescription Medicines Code of Practice Authority

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 pharmaceutical industry is highly regulated. 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.

In stark contrast, digital communication such as social networking sites, twitter, blogs, discussion forums, user generated copy and Wikipedia are largely seen as 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.

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. 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 etc. 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 would 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 list 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 made in response to individual enquiries from health professionals or appropriate administrative staff 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 in response to an unsolicited enquiry. A reply that can take the benefit of this exemption 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 9.9 states that the 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 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 22 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 their 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 22.2 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 information 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 Clinical 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 22 differentiates between proactive information which is pushed at the recipients (for example advertisements in journals etc) reference information as detailed above and reactive information which is supplied to the public in response to a direct request.

Clause 22 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 is given in the supplementary information to Clause 22.3.

If a company is working with a patient group then Clause 23 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 being 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) and companies must ensure that all personnel (including those retained by way of contract with a third party) 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. The PMCPA and ABPI have involved a number of organisations in discussions. There have been few complaints about digital communication and thus it has been decided to issue guidance supported by Q&As rather than amend the Code.

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.

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

Yes, providing the material complies with the Code – particularly Clause 22.

3. 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.

4. Can companies run discussion forums?

If a company were to facilitate a discussion forum on a third party website, or host 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.

5. 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 anyway unless all of the content complies with the Code. If a company is working with a patient group then Clause 23 becomes relevant and must be followed including the requirement for a written agreement. 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.

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

This is very important. 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.

7. Can companies correct Wikipedia?

This is difficult and is a question of policy for a company. Simple cross referring 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 22.2) 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.

8. Can companies link to other websites?

This is covered in Clause 24.6. Any website chosen by a company to link to from its website should stand up to scrutiny. 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 includes website addresses in advertising to health professionals etc then the content of that website would be potentially subject to the Code.

9. 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.

10. What about use of blogs?

If a company issues a blog then the content needs to comply with the Code. A blog is a website that can be added to on an ongoing basis. Blogs enable people with a common interest to express their views on the Internet and hear back from and connect with others. Blogs are a popular communication tool for groups to share views and ideas and could be established for use either by groups of health professionals or patients.

If a company were to sponsor a blog about a medicine or a therapy area, then it would need to be careful to ensure that all of the information contributed complied with the Code and declare its sponsorship. It would be unacceptable, for example, if someone contributed material to a blog about the unlicensed use of a product if that blog had been 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.

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.

11. 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.

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

Yes. Meetings have to comply with Clause 19 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.

13. 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 is made this would be taken up with the local company.

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

Clause 24.2 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.

Recently 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 24.2. 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 which applies to the country where the parent company or affiliate generating the tweets resides.

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.

October 2012

PMCPA Prescription Medicines Code of Practice Authority
7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: 020 7747 8880 Fax: 020 7747 8881 Email: info@pmcpa.org.uk **www.pmcpa.org.uk**